AnimalhealthEurope comments to EMA Scientific Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed (EMA/CVMP/508559/2019).

Final, 26 November 20

General Comments:

AnimalhealthEurope welcomes the opportunity to provide comments to the EMA Scientific Advice. Oral medication via other forms than medicated feed is a form of treatment that is still used and important in a number of member states. Adequate Guidance should be in place to ensure safe and efficient use of those Veterinary Medicinal Products (VMPs). The safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed often requires specific technological equipment on the farm and special knowledge of the user. **The development of a good practice guide is therefore useful and supported from our side**.

Whereas drinking water medication and the group treatment of animals is considered suitable in most parts of the text, in the introduction and recommendation the restriction for 'Individual animals only' is not only suggested for VMPs to be administered via top dressing but also for other VMPs authorised for oral medication via solid feed. **We think this is inappropriate and overly restrictive**. Most of the products authorised for oral medication via solid feed have been authorised for treatment of groups of animals and all will have proven to be efficacious. It should also be kept in mind that not every active substance is suitable for application via drinking water.

Several of the recommendations if implemented will require changes to package labels and leaflets. It is important that **reasonable timelines** are set for the implementation of any changes, for example allowing these to be implemented at the next label/leaflet change.

Some of the recommendations if applied retrospectively could lead to requests to companies to generate new data on old products. Such requests always risk the future availability of some products, especially those aimed at smaller markets/minor uses. Hence, any request for generation of **new data should be justified** through evidence of a risk for that particular product.

Considering the large variations in farms and farming systems e.g. infrastructure, within and between countries, any recommendations which will impact farms will need to be carefully evaluated and discussed with COPA-COGECA to understand whether they are practical or not.

Detailed comments and proposed wording

In the following section we share our specific comments to the details of the EMA advice. We also suggest amendments to the wording of certain paragraphs on the presumption that, while the EMA advice itself will not be amended, the meaning of this text may be carried forward into the draft Delegated Act. Specific wording proposals are often a good way to illustrate the precise meaning of a written comment.

Specific Comments:

Page/Section Number	Comment
3/Overview of the recommendations *Para 2*	**Comment:** Whereas it is considered suitable that top dressing of veterinary medicinal products (VMPs) in form of oral powders, granules or similar pharmaceutical forms should be limited to individual animals only, a number of technologies are available to ensure adequate dosing for a greater number of animals. Therefore, a general restriction of the use of VMPs in form of oral powders, granules or similar pharmaceutical forms to individual animals is not justified. In case adequate dosing is demonstrated, mixing of a VMP into the ordinary feed should remain an option for treatment of groups of animals. This comment applies to several paragraphs as indicated below* (See also 4/Overview of the recommendations, Para 3 and also p11 1.7 Rationale, 3.2) **Proposed change:** It is recommended that in veterinary medicines the use of ~~oral powders, granules or similar pharmaceutical forms administered to terrestrial animals via solid feed~~ **veterinary medicinal products administered via top dressing** shall be restricted to individual animals only. ~~This includes veterinary medicinal products administered via top dressing.~~
4/Overview of the recommendations *Para 2*	**Comment:** A recommendation is made to highlight that potential interactions between commonly used biocides and VMPs administered via drinking water should be assessed and appropriate guidance regarding interactions and incompatibilities should be provided in the product information. It is not considered appropriate or practical to ask the pharmaceutical industry to conduct studies to examine every possible interaction between biocides and VMPs that may be used in drinking water systems. **Proposed change:** If VMPs carry warnings that they should not be added to drinking water which has been treated with biocides then the need for such assessments and guidelines should be negated. "Good Practice Guide" for farmers should also provide guidance on cleaning and maintaining drinking water lines including the need to ensure before addition of veterinary medicines residues of biocides are not present (for example through appropriate flush through and system design principles).
4/Overview of the recommendations *Para 3*	**Comment**: *The same comment above applies (3/ Overview of the recommendations, Para 2). In case adequate dosing is demonstrated mixing of a veterinary medicinal product into the ordinary feed should remain an option for treatment of groups of animals. The development of a good practice guide defining the necessary technological equipment and training of users is fully supported. **Proposed change:** In summary, the advice provides recommendations for the use of veterinary medicinal products for oral administration other than medicated feed in a manner that ensures their safety and efficacy by e.g. **developing a good practice guide ensuring the necessary technological equipment and knowledge of the user is in place and** recommending that oral veterinary medicinal products to be **administered via top dressing** ~~mixed with feed at farms~~ are limited to use for individual animals, and by providing better information and training for those administering the products to animals, as well as recommending measures to minimise antimicrobial resistance and exposure of the environment.

7/1.Recommendations *1.1. Oral powders administered via feed* *Para 1*	**Comment:** *The same comment above applies (3/ Overview of the recommendations, Para 2). Taking this into account the restriction to individual animals is not justified. In case adequate dosing is demonstrated administration of a veterinary medicinal product via the ordinary feed should remain an option for treatment of groups of animals if justified (see general comment above). **Proposed change:** Recommendation: **For the use of** oral powders, granules or similar pharmaceutical forms administered to terrestrial animals via solid feed **a good practice guide ensuring the necessary technological equipment and knowledge of the user should be developed**. ~~including~~ ~~v~~ Veterinary medicinal products via top-dressing shall be restricted to use in individual animals only.
7/1.Recommendations *1.1. Oral powders administered via feed* *Para 2*	**Comment:** *The same comment above applies (3/ Overview of the recommendations, Para 2). It has been demonstrated that uniform and also high blood level values can be achieved in a group of animals e.g. resulting from continuous feed intake, even if complete homogeneity is not given. (A Wehrend, P Latell, F-P Ungemach, Leipziger Tierärztetag 2010; H Gerlings 2013). These effects resulting from repeated feed intake have also been confirmed in a Monte Carlo Simulation. **Proposed change:** Rationale When administering medicines mixed into animal feed for a group of animals, **it must be ensured** ~~the mixture must be homogeneous to ensure~~ that each animal receives the same and correct dose in their feed. In view of the volume of the feed used for group treatment, as well as the large variety of animal feed and feeding systems used, **it is important that appropriate technological equipment is in place** ~~not considered possible~~ to ensure **adequate dosing and** ~~such homogeneous~~ distribution of an oral powder, granules or similar pharmaceutical forms in dry feed. The result of a non-homogeneous mixture could be over- or under-dosing of the animals; this is a particular concern, if larger amounts of feed with a veterinary medicinal product are to be prepared for groups of animals that might also compete for the feed. ~~For groups of animals, the administration of an oral powder, granules or similar pharmaceutical form via feed is therefore generally not considered appropriate.~~
7/1.Recommendations *1.1. Oral powders administered via feed* *Para 4*	**Comment:** *The same comment above applies (3/ Overview of the recommendations, Para 2). Therefore, a general restriction of the use of veterinary medicinal products in form of oral powders, granules or similar pharmaceutical forms to individual animals is not justified. In case adequate dosing is demonstrated mixing of a veterinary medicinal product into the ordinary feed should remain an option for treatment of groups of animals. **Proposed change:** The administration of an oral powder, granules or similar pharmaceutical forms in feed **to groups of animals should be allowed if the necessary technological equipment is available at the respective holding and the animal holder is adequately trained**. ~~or via t~~Top-dressing is, ~~however,~~ considered to be acceptable **only** for individual animals, as ~~here the uptake of the feed with the medication can be better controlled, and the homogeneity of the mixture of the veterinary medicinal product (oral powder) and feed is of lesser concern,~~

	~~as~~ the animal would be expected to take up all the allocated amount of medication~~. If a number of animals are to be treated, the medication should be prepared and administered to each individual animal separately~~. The specific use of an oral powder, granules or similar pharmaceutical form in feed or via top dressing should be substantiated by appropriate studies, provided and assessed during the marketing authorisation procedure. ~~Only products for which in-feed use or administration via top-dressing is clearly provided for in the product literature may be used as such.~~
8/1.Recommendations *1.3. Pack Size*	**Comment:** The proposal that for orally VMPs only pack sizes considered appropriate for the number of animals to be treated, the recommended posology and the characteristics of the target population shall be authorised needs to allow for the large variations in animal size, group numbers, posology for different diseases, and administration systems.
9/1.Recommendations *1.3. Pack Size* *Para 3*	**Comment:** The grounds for refusal of a MA are already set out in the new Regulation (article 37) and these do not include unsuitable pack sizes and it is understood no change to the Regulation can be expected in the foreseeable future. Whilst acknowledging pack size is important, equally important is availability and the viability of a range of pack sizes has to be taken into account.
9/1.Recommendations *1.5. Responsibility of the animal keeper*	**Comment:**....expired veterinary medicinal products are not used and are correctly discarded**.** This is the situation for all VMPs regardless of the route of administration and the reiteration here is superfluous. Although as an industry we would support the reiteration of advice on the correct disposal of VMPs to the veterinarians and animal owners.
10/1.5. Responsibility of the animal keeper *Rationale* *Para 2*	**Comment:** Provisions should be in place to achieve a *similar level* of safety and quality with regard to cross-contamination and ensure a secure disposal. Due to the different nature and equipment measures to achieve this might differ. **Proposed change:** In order to ensure an adequate administration of the veterinary medicinal products to the animals, minimise cross-contamination and ensure a secure disposal, the ~~rules~~**requirements** for farmers ~~when~~ **for** administering veterinary medicinal products via the oral route should **ensure a similar level of quality and safety** ~~be as strict~~ as when administering medicated feed ~~to food-producing animals~~.
10/1.Recommendations *1.6. Cleaning of feeding and watering systems*	**Comment:** .....cleaning and sanitising shall be used according to instructions. This statement is open to interpretation; is this according to the instructions of the VMP or the instructions for the cleaning and sanitising product? **Proposed change:** Please clarify
11/1.7 Development of a "Good Practice Guide" for farmers	**Comment:** The development of such guidance is fully supported. Good examples for such Guidance are existing in member states e.g. Germany (BMEL Leitfaden Orale Anwendung von Tierarzneimitteln im Nutztierbereich über das Futter oder das Wasser, 2nd Edition, May 2014, BMEL Guidance on oral medication of veterinary medicinal products for food producing animals 2nd Edition May 2014) **Proposed change:** A Good Practice Guide should be developed for farmers on the use of veterinary medicinal products administered orally other than via medicated feed. **There are already good examples for such Guidance in member states e.g. Germany (BMEL Leitfaden Orale Anwendung von Tierarzneimitteln im Nutztierbereich über das Futter oder das Wasser, 2nd Edition, May 2014, BMEL Guidance on oral medication of veterinary medicinal products for food producing animals 2nd Edition May 2014)**
12/1.8. Concomitant use	**Comment:** Potential interactions between commonly used biocides and veterinary medicinal products administered via drinking water should be

of biocides and medicated water	considered and appropriate guidance regarding interactions and incompatibilities should be provided in the product information In case there is no detailed information a warning not to use biocides concurrently should suffice. In addition, it should be ensured that only biocides licensed for use in drinking water are used. The recommended Good Practice Guide should include advice which will avoid biocides or their residues being present at the time when VMPs are added to drinking water **Proposed change:** Potential interactions between commonly used biocides and veterinary medicinal products administered via drinking water should be assessed and appropriate guidance regarding interactions and incompatibilities should be provided in the product information. **In case there is no detailed information a warning not to use biocides concurrently should be included in the leaflet.**
Page 21-22/ Poultry **Page 22/Pigs,** *Para 1* **Page 37/ Feed hygiene legislation – Cleaning of feeding equipment /watering system,** *Para 2*	**Comment**: The use of stabilisers such as skimmed milk is mentioned for vaccines intended for pigs on page 22 and not for vaccines intended for poultry in pages 21-22. However, they are mentioned for poultry vaccines only on page 37. **Proposed change:** please correct the inconsistency between the different sections.
25/3.2 Oral Powders *Para 2*	**Comment:** *The same comment above applies (3/ Overview of the recommendations, Para 2)**.** **Proposed change:** In order to correctly mix the veterinary medicinal product into the feed, special mixing equipment, dosing systems and/or the need to prepare a "pre-mixture" might be required. **On the market suitable dosing equipment is available for dosing via water as well as via feed that has been tested and approved to defined standards (Reference: DIN 10529-1, DIN 10529-2).** Alternatively, the powder can be sprinkled on top of the feed (top-dressing use), which is done with the intention to ensure that the complete dose of the medication is consumed by the animal *(see also section 3.3.2 on top-dressing).*
26/3.2 Oral Powders	**Comment:** *The same comment above applies (3/ Overview of the recommendations, Para 2). On the market suitable dosing equipment is available for dosing via water as well as via feed that has been tested and approved to defined standards (Reference: DIN 10529-1, DIN 10529-2). So the restriction to individual animals is not justified. In case adequate dosing is demonstrated administration of a veterinary medicinal product via the ordinary feed should remain an option for treatment of groups of animals if justified. **(see comment section Overview of Recommendations and Section1.1)** It has been demonstrated that uniform and also high blood level values can be achieved in a group of animals e.g. resulting from continuous feed intake, even if complete homogeneity is not given. (A Wehrend, P Latell, F-P Ungemach, Leipziger Tierärztetag 2010; H Gerlings 2013). These effects resulting from repeated feed intake have also been confirmed in a Monte Carlo Simulation. **Proposed change:** When administering medicines mixed into animal feed for a group of animals, **it must be ensured** ~~the mixture must be homogeneous to ensure~~ that each animal receives the same and correct dose in their feed.

	In view of the volume of the feed used for group treatment, as well as the large variety of animal feed and feeding systems used**, it is important that appropriate technological equipment is in place** ~~not considered possible~~ to ensure **adequate dosing and** ~~such homogeneous~~ distribution of an oral powder in dry feed**. On the market dosing equipment is available for dosing via feed that has been tested and approved to defined standards (Reference: DIN 10529-1).** The result of a non-homogeneous mixture could be over- or under-dosing of the animals; this is a particular concern, if larger amounts of feed with a veterinary medicinal product are to be prepared for groups of animals that might also compete for the feed. ~~It is therefore considered that the use of oral powders for in-feed use should be restricted to individual animals. If a number of animals are to be treated, the medication should be prepared and administered to each individual animal separately.~~ ~~...~~ ***Special considerations for the safety and efficacy assessment*** The result of a non-homogeneous mixture (see above, quality) could be over- or under-dosing of the animals; this is a particular concern, if large amounts of solid feed with a veterinary medicinal product are to be prepared for groups of animals that might also compete for the feed (see section 6.1 – dose). Therefore, for groups of animals, the use of an oral powder administered via solid feed, but not via medicated feed, **will need specific provisions to ensure every animal receives the correct dose.** ~~is generally not considered to be appropriate. Instead, administration of veterinary medicinal products via medicated feed or drinking water or liquid feed should be the recommended routes of administration for the group treatment of animals.~~ **In general** ~~The administration of an oral powder into solid feed is , however, considered to be acceptable for individual animals,~~ ~~as here~~ the uptake of the feed with the medication **by an individual animal** can be better controlled, and the homogeneity of the mixture of the veterinary medicinal product (oral powder) and feed is of lesser concern, as the animal would be expected to take up all the allocated amount of medication. In regard to the treatment of small numbers of animals, it is understood that this concerns animals which could be fed individually (e.g. individual sows in farrowing units, or animals kept purely for non-commercial purposes).
28/3.3.2 Administration via liquid feed *Para 1*	**Comment:** The section number cited for veterinary medicinal products used in milk is erroneous. **Proposed change:** Section 4.2 to be replaced by section 4.5**.**
28/ 3.3.2. Administration via liquid feed *Para 3*	**Comment:** It might also be appropriate to have it incorporated in feed first and then add water. Regarding solid feed see comments above. **Proposed change:** Most of the concerns considered above for the in-feed use of oral powders would also apply for the use of oral powders in liquid feed (e.g. homogeneity, compatibility). ~~However, unlike oral powders used in dry feed, I~~ **I**t is considered that homogeneity could be achieved in liquid feed **following provided preparation instructions.**, ~~provided the following steps are taken: the veterinary medicinal product should first be mixed into the liquid base (e.g. into (drinking) water) used to prepare the liquid feed, and then mixed into the final feed.~~ Apart from considerations for in-feed use, the assessment of veterinary medicinal products used in liquid feed **might** ~~would~~ therefore also need to consider aspects generally assessed for in-drinking water use, such as: solubility/insolubility in water (of different qualities), instability (in water) ,**if applied via the water component,** interactions with biocides/acids (e.g. chloride water)/biofilms and quality of water (see

	section *4.2 – Quality of water used*)). In addition, homogeneity, stability and solubility would impact on other aspects such as dosing and cross-contamination, cleaning of equipment, as addressed in other sections of this report. This could be addressed in guidance published by the Agency. For oral powders, granules or similar pharmaceutical forms intended for administration via liquid feed, the product information must carry clear information about the preparation and mixing/dissolution of the veterinary medicinal product into liquid feed. Under these circumstances, it is considered that oral powders can ~~still~~ be used for group treatment via liquid feed~~; i.e. only oral powders administered via **solid** feed should be authorised for use in individual animals only (*see section 3.2 – oral powders*).~~
30/3.4.1 Tolerance levels	**Comment:** An adequate dosing has to be ensured, adapted to the processes and needs on the farm. As storage and transport is usually minimised there is no need to provide studies on this. With regard to homogeneity see comments above: There is technological equipment available for dosing via water as well as via feed that has been tested and approved to defined standards (DIN). This should be taken into account. It has been demonstrated that uniform and also high blood level values can be achieved in a group of animals e.g. resulting from continuous feed intake, even if complete homogeneity is not given. (A Wehrend, P Latell, F-P Ungemach, Leipziger Tierärztetag 2010; H Gerlings 2013). These effects resulting from repeated feed intake have also been confirmed in a Monte Carlo Simulation. **Proposed change:** For group treatment **adequate dosing and** ~~a homogeneous~~ mixture of feed and veterinary medicinal product is required **so that it is ensured that every animal to be treated receives the correct dose**. In the feed ration for an animal, the actual amount of active substance incorporated in the feed (either via medicated feed or as veterinary medicinal product) might vary. Annex IV of Regulation (EU) 2019/4 sets tolerances allowed for discrepancies between the nominal content of an active substance of the veterinary medicinal product in a medicated feed and the actual content. These discrepancies are caused e.g. by technical limitations of the mixing process and the equipment used, by the nature of the feed ingredients (e.g. abrasive substances for pre-mixture), or by aggressive pelleting conditions such as high temperature. For antimicrobial active substances a tolerance of 10 % is applicable. For other active substances, permitted tolerances in the medicated feed are given of 10-20 % depending on the final concentration of the active substance in the feed, i.e. a minimum amount of 80 or 90 %, and a maximum amount of 110-120 % of the nominal content would be acceptable. Compliance with the tolerance levels are checked in the feed mill after manufacturing. Tolerances and homogeneity in feed have to be evaluated in the dossier for the premix for medicated feed in the context of assessing mixing instructions, stability, segregation during transport etc. **In principle** the same considerations could also apply for veterinary medicinal products administered in feed other than via medicated feed, when administered for group treatment ~~(e.g. in fish treatment, where other routes of administration like in water use are not an option, and in group treatment via liquid feed).~~ **recognizing that storage and transport is usually minimised in use at the farm.** However, e.g. for oral powders mixed into feed, there is currently no clear guidance for applicants or assessors on tolerance levels or incompatibilities that are to be assessed, or information to be provided to the end user on dosing and mixing instructions, and subsequent handling of that feed, to ensure accurate dose delivery and, to the extent possible, that the

	recommended treatment dose is consumed by individuals in the treated group. **It has been demonstrated for administration to a group of animals that a certain variability regarding the mixing into feed has no major impact on the blood levels. This is e.g. resulting from continuous feed intake. Studies have shown that adequate blood levels can be reached although a complete homogeneity is not given. (A Wehrend, P Latell, F-P Ungemach, Leipziger 2010; H Gerlings 2013). These effects resulting from repeated feed intake have also been confirmed in a Monte Carlo Simulation.**
32/ 4.3. Concomitant use of biocides	**Comment:** The use of biocides can not only have negative impact but also a number of positive effects and contribute to safety of use as they prevent biofilms in the system**.** **See comment to 1.8** Known interactions should be mentioned in the product information leaflet. It is not possible to perform studies on concomitant use of every type of biocides during the authorisation procedure of a VMP intended for drinking water medication as there is a broad number of biocidal products in the market. In case there is no detailed information a warning not to use biocides concurrently should suffice. In addition, it should be ensured that only biocides licensed for use in drinking water are used. **Proposed change:** Routine discontinuation of biocide use prior to treatment may have adverse /unintended consequences related to contamination/biofilm formation etc. The stability of medicated water in the presence of biocides should therefore be considered during the assessment of veterinary medicinal products administered via drinking water, milk or liquid feed. However, compatibility with biocides is currently neither addressed nor requested, as it is not mentioned in the CVMP guideline on "Quality aspects of pharmaceutical veterinary medicines for administration via drinking water" (EMEA/CVMP/540/03 rev 01. Potential interactions between commonly used biocides and veterinary medicinal products administered via drinking water should be investigated and assessed, and appropriate guidance regarding interactions and incompatibilities be provided in the product information **whenever possible. Considering that local differences exist in the concomitant use throughout the member states and that a variety of biocidal products may be on the market, it is acknowledged that not every combination can be tested. In case there is no detailed information a warning notice on using biocides concurrently should be included in the product information.**
33/4.4 Concomitant use of solubility enhancers	**Comment:** Solubility enhancers do also contribute to safety of use as they prevent biofilms and deposits in the system. **Proposed change:** Some oral powders are poorly soluble in drinking water, and in order to achieve better homogeneity in the water, farmers or veterinarians might use solubility enhancers to improve the solubility of the veterinary medicinal product. **Such solubility enhancers can also contribute to safety of use being an effective measure to prevent deposits and development of biofilms in the pipes**.
35/ 6.1 Dose *Para 4*	**Comment:** Depending on the type of product, detailed information should be included in the product information relating to the mixing of the veterinary medicinal product into (different types of) feed/drinking water, use of dosing equipment, and cleaning of the dosing equipment, taking into account risks raised elsewhere in the report. Given the wide variety of commercial systems available on the market is it practical to cover all possibilities in the product information.

36/6.2 Cross contamination	**Comment:** The need for regular cleaning and treatment against biofilms has been discussed and agreed. Awareness by vets and farmers has been continuously improved over the past years at least in some member states. These efforts of continuous education should be continued to ensure further improvement in all member states. Solubility enhancers can also contribute to safety of use as they prevent biofilms and deposits in the system. **see also comment 4.4** **Proposed change:** Administration of veterinary medicines via drinking water, milk, milk replacer and liquid feed (e.g. antibiotics or vaccines given together with skimmed milk or other stabilisers) may result in the formation of sediment in the pipelines, and this could potentially cause the formation of biofilms (bacteria) or residual traces of antibiotics. Limited information is available on the extent of this problem, **e.g. with regard to** ~~such as~~ the length of time residues of veterinary medicinal products are present in water (cross-contamination) **and the** ~~, and if there is a~~ potential for development of resistant bacteria. Bacteria can also develop resistance to biocides, which might co-select for antimicrobial resistance in the environment. **Therefore regular cleaning and treatment against development of biofilms is highly recommended. (see also 4.4)**
39/6.6 Environmental Safety	**Comment:** Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products. All VMPs regardless of the route of administration should be correctly disposed of in accordance with the relevant national legislation. As an industry we would support the provision of advice on the correct disposal of VMPs to the veterinarians and animal owners by the national authorities. **Proposed change:** the provision of advice on the correct disposal of VMPs to the veterinarians and animal owners by the national authorities should be considered.
44-46/References	**Comment:** the following references should be added, see comments above. **Proposed change:** please add BMEL Leitfaden Orale Anwendung von Tierarzneimitteln im Nutztierbereich über das Futter oder das Wasser, 2nd Edition, May 2014, BMEL Guidance on oral medication of veterinary medicinal products for food producing animals 2nd Edition May 2014) https://www.bmel.de/SharedDocs/Downloads/DE/_Tiere/Tiergesundheit/Tierarzneimittel/Leitfaden-Orale-Anwendung-Tierarzneimittel.pdf DIN 10529-1 Dosiersysteme für die orale Verabreichung von pulverförmigen oder flüssigen Fertigarzneimitteln bei Nutztieren- Teil 1: Dosiersysteme für pulverförmigge Fertigarzneimttel zur Verabreichung über mehliges Futterr, DIN 10529-1 Dosing apparatus for the oral medication of powdery or liquid proprietary medicinal products at farm livestock – Part 1: Dosing apparatus for powdery proprietary medicinal products for application about powdery feed DIN 10529-2 Dosiersysteme für die orale Verabreichung von pulverförmigen oder flüssigen Fertigarzneimitteln bei Nutztieren- Teil 2: Dosiersysteme für Fertigarzneimttel zur Verabreichung über das Trinkwasser, DIN 10529-2 Dosing apparatus for the oral medication of powdery or liquid proprietary medicinal products at farm livestock – Part 2: Dosing apparatus for liquid proprietary medicinal products for application about drinking water

	GERLINGS, H. Praktische Hinweise zur Durchführung einer oralen Medikation via Flüssigfutter, Vortrag, Tierärztliche Hochschule Hannover, 13.06.2013 WEHREND, A., P. LATELL u. F. R. UNGEMACH (2010): Blutspiegel von Antibiotika bei Verwendung eines handelsüblichen Medikamentendosierer für Trockenfütterung in: 5. Leipziger Tierärztekongress, Leipziger Blaue Hefte Proc. Leipzig 21.-23.01.2010. Bd. 2, S. 450-453
50/Annex II ***Use of measuring/dosing /mixing devices***	**Comment:** There is technological equipment available for dosing via water as well as via feed that has been tested and approved to defined standards (Reference to DIN: DIN 10529-1 Dosiersysteme für die orale Verabreichung von pulverförmigen oder flüssigen Fertigarzneimitteln bei Nutztieren- Teil 1: Dosiersysteme für pulverförmigge Fertigarzneimttel zur Verabreichung über mehliges Futterr, DIN 10529-1 Dosing apparatus for the oral medication of powdery or liquid proprietary medicinal products at farm livestock – Part 1: Dosing apparatus for powdery proprietary medicinal products for application about powdery feed DIN 10529-2 Dosiersysteme für die orale Verabreichung von pulverförmigen oder flüssigen Fertigarzneimitteln bei Nutztieren- Teil 2: Dosiersysteme für Fertigarzneimttel zur Verabreichung über das Trinkwasser, DIN 10529-2 Dosing apparatus for the oral medication of powdery or liquid proprietary medicinal products at farm livestock – Part 2: Dosing apparatus for liquid proprietary medicinal products for application about drinking water **Proposed change:** The SPC and product literature should contain clear instructions on the mixing of the veterinary medicinal product into feed or drinking water, taking into account the bodyweight range of animals to be treated, ~~dispensing machines,~~ and on the information required for veterinary medicinal products likely to be administered using special dosing equipment. However, in view of the large variety of dosing / mixing as well as watering / feeding equipment available, there are limitations on the details that can be included in the product information. **On the market dosing equipment is available for dosing via water as well as via feed that has been tested and approved to defined standards (Reference to DIN: DIN 10529-1, DIN 10529-2)** Dosing equipment, which cannot guarantee **adequate dosing** ~~homogeneous mixing~~ of feed **or water** and veterinary medicinal product should be avoided.