21 February 2018
EMA/619729/2017
Veterinary Medicines Division

Overview of comments received on 'Guidance on collection and provision of national data on antimicrobial use by animal species/categories' (EMA/489035/2016)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1.	Responsible Use of Medicines in Agriculture Alliance (RUMA)
2.	Taskforce ABRES porcine workgroup (POV)
3.	Federal Office of Consumer Protection and Food Safety (BVL) and Institute for Risk Assessment (BfR)
4.	Norwegian Food Safety Authority (NFSA) in cooperation with Veterinary Institute
5.	Swiss Federal Food Safety and Veterinary Office (FSVO)
6.	Finnish Food Safety Authority (EVIRA)
7.	Expert panel of the Netherlands Veterinary Medicines Institute (SDa)
8.	Swedish Board of Agriculture
9.	Fédération Européenne pour la Santé Animale et la Sécurité Sanitaire (FESASS)
10.	Federation of Veterinarians of Europe (FVE)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. General comments – overview

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1.	RUMA has been arguing for many years that decisions on controlling the use of antibiotics in agriculture should be based on sound evidence so we welcome the continuing good work of ESVAC in collecting antibiotic usage data. It is necessary to evaluate the impact of reduced antibiotic use not just on AMR levels but also on the health and welfare of the animals and we think this should form part of ESVAC's role.	Thank you for your comments. Monitoring animal health and welfare are considered to fall outside the scope of EMA/ESVAC.
2.	Dear members of the EMA committee, On behalf of the Taskforce ABRES porcine workgroup I would like to respond to the EMA document 'Guidance on provision of data on antimicrobial use by animal species from national data collection systems'. The ABRES workgroup deals with all subjects related to antibiotic usage and antimicrobial resistance in the Dutch pig sector. With this letter I would like to comment on the EMA document and point out the concerns of the ABRES workgroup. The specific document describes EMA's intentions on how to describe and monitor antibiotic usage in some animal production sectors in the European Union. The proposed calculation method is different from the method used in the Netherlands by the Veterinary Medicines Institute (SDa). The most relevant difference is the fact that EMA uses the number of kilograms of animals produced on the basis of an average weight per animal (DDDvet/PCU), whereas the SDa uses the average number of animal sites over one year multiplied by the average weight of an animal (DDDAnat). The EMA gives us an insight in the exposure of antibiotics correlated to the production results. The SDa approach seems to be a representation of the exposure of the animal's intestinal flora to antibiotics, thus showing a correlation with the antibiotic resistance patterns in the specific sector. However, the SDa approach results in significantly higher values for antibiotic usage than the EMA approach. For the Dutch pig sector the SDa value is	Thank you for your comments. Although comparison of antimicrobial use between countries is not the primary objective of the data collection, it is acknowledged that direct comparison between countries is not possible if the data for the different countries are not harmonised and standardised, e.g. if the results are presented with a different denominator. - Point 1: A sentence has been added to Chapter 3.1 of the guidance document. - Point 2: Comparison between countries is not the primary objective of the guidance nor the data collection, but harmonisation and standardisation – to the extent possible – of the collected data is. Any reporting of

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	roughly twice as high as the EMA value. As a consequence it is impossible to compare both values (DDDAnat and DDDvet/PCU). The ABRES workgroup recognizes the importance of an international standard for measuring antibiotic usage, which enables a comparison between different member states. At the same time, the SDa calculation method is an established method in the Netherlands. We would like to emphasize the fact that a comparison of the values based on the two different calculation methods is not possible. Therefore we have the following requests: 1. In every publication on antibiotic usage in animal production sectors the applied calculation method should be clearly mentioned. 2. When comparisons between member states are made, it is of great importance that the calculation method is the same for each country. If numbers on antibiotic usage in the Dutch pig sector, based on the SDa method, are compared with those in other European countries (based on the EMA method), it will seem that the use of antibiotics in the Netherlands is unfairly high. This is something we want to avoid, especially given the fact that we managed to reduce the antibiotic usage over the past few years significantly. We kindly ask you to take our requests in consideration. Of course we are willing to explain questions which may result from this letter. Thanking you in advance.	results by EMA/ESVAC would be based on the methodology described in the guidance, and therefore the calculation method would be the same for each country for which results are reported.
3.	**Comment:** EMA provides two documents, the guidance document (EMA/489035/2016) itself and a document answering questions (EMA/716249/2016). This is a quite confusing approach, as inconsistencies between the documents are hardly avoidable. This comment relates to lines 49-50, 85-89, 326-514. **Proposed change:** Combine the two documents to one consistent document, with a main part describing the proposed data collection system and annexes giving examples for successful implementation taking into account the comments given below.	Thank you for your comments. The Q&A document is intended to provide more detail on the background of decisions taken with regard to the guidance and which are considered outside the scope of the guidance. Discussions with stakeholders during

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		the drafting process have indicated that the main body text of the guidance document should be short and concise. Therefore the two documents are kept. Annex 6 contains links to reports and guidelines on antimicrobial use data collection for those that would like to have examples of or information on existing data collection systems.
3.	**Comment:** Document EMA/489035/2016 reflects that is quite unclear how to establish procedures to ensure a high level of data quality which can be met by all countries and which overcome the limitations of the data collection based on sales data. This comment relates to lines 54-58, 81-84, 101-106, 107-114, 181-183, 223-226, 226-230, 244-249, 257-265, 273-276, 278-314. **Proposed change:** We suggest to envisage a stepwise approach. In a first step, countries should be motivated to report data on antimicrobial use by animal species. Minimal requirements for this type of reporting should be clearly described. These data and experiences should be used in a second step, to develop, agree on and publish procedures how data can and should be validated. Furthermore, procedures should be developed on how comparability can be ensured. Only after this second step, data from those countries which can comply with this should be summarised in a report where data are compared (third step). To achieve this, also a procedure for collection of denominator data in a standardised and unbiased way should be developed, agreed on and published. There, the limitations of the suggested "biomass" approach should be addressed and the bias introduced should be assessed before fixing the approach taken for the new reporting system. As a consequence, in this document a new chapter should be drafted where this stepwise approach is described. Paragraphs which currently talk about "harmonised data	One of the objectives of ESVAC is to foster the collection of such data in EU/EEA countries. The guidance is one of the outcomes of that objective. The first and second steps as proposed are included in the guidance, Chapters 1 and 2. Previously, a preliminary trial was performed on pig farms in ten volunteer MSs from among the ESVAC network to test a protocol and templates for data collection on antimicrobial use and animal population on these farms (a report of this trial can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/05/WC500206990.pdf). Experience and lessons learned from this trial were taken into account during the drafting

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	collection" and "calculation of indicators" should be revised or removed as this should be only performed for data with comparable data quality and only after finalising the second step of the system development.	of the guidance document. As detailed in the Q&A document, the guidance document is not a protocol. The guidance is intended to be informative for those wanting to collect use data by species. The guidance intends to set standards, not requirements, to prepare for a future requirement for collection of antimicrobial use data by species. As the data will remain property of the MSs providing the data, quality control and validation of the data are the responsibility of those MSs. Chapter 3 of Annex 2 addresses data integrity and quality control. Furthermore, EMA produces a certain validation and data quality check while processing the received data. It is acknowledged that it takes up to several years for any data collection system to be fully established, with high quality and validated data. The ESVAC sales data reports include the number of years countries have provided data to EMA. A similar table would be included in any report by EMA/ESVAC on use data by species.

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		Denominator data are proposed (for the census approach) to be collected from Eurostat and TRACES – these data are harmonised, standardised and validated. In the case of Eurostat these data are also publicly available.
3.	**Comment:** The current draft says that for data management purposes and to ensure completeness of the data, antimicrobial use data would have to be provided to EMA by use of a template developed and provided by the ESVAC team, in the form of number of packages used per veterinary medicinal product (VMP) presentation per animal species/category in the MS. But there is no rationale given why data have to be provided by packages, as this introduces bias into the data collection and reporting. This comment relates to lines 70-73, 73-77, 212-214. **Proposed change:** To ensure consistency with national approaches the amount (kg) of the antimicrobial substance should be the basis for data collection and reporting. This should be already revised for the first step of development of the new data collection system.	In addition to the benefits for data management and completeness of data, the use of 'number of packages' is based on the experience of collecting sales data for ESVAC and on experience of organisations already collecting use data by species. The option of providing data in the form of 'weight or volume of VMP' has now been added to the guidance. From these data the quantity of active substance can be calculated by EMA in a harmonised manner (e.g. harmonised conversion factors). However, what is not accepted is the provision of data as quantity of active substance (i.e. independently of the VMP used) as this would complicate validation of the data received at EMA.
4.	The Norwegian Food safety Authority (NFSA) welcomes the draft guidelines and thanks for the opportunity to provide comments.	Thank you for your comments.

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4.	Art. 54 of the proposed regulation governing veterinary medicinal products (VMPs) adopted by the European Commission on 20 September 2014 (COM(2014) 558 final) (http://ec.europa.eu/transparency/regdoc/rep/1/2014/EN/1-2014-558-EN-F1-1.Pdf) includes a requirement for European Union/European Economic Area (EU/EEA) countries to collect and supply to the European Medicines Agency (EMA) data on sales and use of antimicrobials. In Art. 54, point 3 reads: *"The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish detailed rules on the methods of gathering data on the use of antimicrobials and the method of transfer of these data to the Agency".* In the guidance it reads "…wishing to do so", "….wanting to provide data", "is not mandatory" etc. NFSA interpret that these phrasings are included to open up for call for data before the regulation and delegating act comes into force (voluntary submission of by species data on antimicrobial use to EMA) but suggest that such phrasing is not appropriate in a guideline and recommend to rephrase/delete it throughout the document.	One of the objectives of the guidance is to inform which data may need to be provided to EMA if the revised regulation comes into force. As it is currently unknown which exact requirements will be included in the final revised legislation of VMPs, the guidance is informative and not binding. This needs to be reflected by the phrasing. Exact and/or binding legal requirements are expected to be included in the delegating/implementing acts. In addition, guidance documents usually include indicative recommendations.
4.	The guidance covers four animal species, and for cattle three production categories – i.e. a total of six species/production categories. Furthermore, it is suggested to provide the data to EMA annually. Although it reads "covers" in the text (line 181) NFSA fear the guidance will be interpreted as a recommendation. Huge amount of resources would be needed at national level in order to provide six datasets to EMA annually, including resources needed for commenting on the reporting of the data. NFSA suggests that the most important arena in order to contain AMR is at national level and that the often limited resources should be used for that purpose. Hence, the position of NFSA is that only the species/categories included in the AMR monitoring as provided under the Commission Implementing Decision (CID 2013/652/EU) and following the same schedule as for providing AMR data to EFSA.	Following discussions with MSs it was agreed that at this stage it was not appropriate to produce a specific recommendation on the species for which data should be collected.
4.	It should be clarified whether data obtained through stratification could be accepted even	Stratification of sales data falls outside

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	if the stratification methodology is not described in the document. This also applies to whether data on sales by antimicrobial substance and form per animal species/production category will be accepted.	the scope of the guidance, which concerns the collection of use data by species. Delivery notes are included as a potential data source; furthermore, the definition given for 'use' in Chapter 4 also includes purchased and delivered antimicrobials. Therefore, sales per animal species/category will be accepted. Furthermore, the guidance has been amended to include the option of providing data in the form of 'weight or volume of VMP'.
4.	It is a need of consistency throughout the document regarding terms used for the animal categories - e.g. sometimes it reads bovine < 1 year of age, other places veal calves.	The use of certain terminology is context specific. Veal calves are a separate category within the bovine animals below 1 year of age. This has now been clarified in Annex 2 table 5.
4.	Ad Chapter 1.2. The guideline consist of two distinct parts: a) which data are proposed to be collected from EU/EEA countries, including facilitating that the data are standardised and harmonised across countries and b) guidance to those countries that are about to set up systems on how the data can be collected to meet this proposal. NFSA suggests that the objectives and scope to be presented/organised according to this.	The objectives and scope are considered to be clear and appropriate. They cover broader aspects which are not all expanded on in the guidance document but are necessary to explain the context of the guidance document.
4.	As Norway has in place continuous electronic surveillance in place with 100% coverage of all farms, NFSA decided to not comment on Annex 4 – Sample surveys.	Comment noted.
5.	The guidance says that "for data management purposes and to ensure completeness of	Thank you for your comments.

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	the data, antimicrobial use data would have to be provided to EMA by use of a template developed and provided by the ESVAC team, in the form of number of packages used per veterinary medicinal product (VMP) presentation per animal species/category in the MS" "Data should be provided to EMA by web-based delivery in the form of number of packages used per VMP presentation (i.e. pack size) in the MS per animal species/categories during the data collection period. Therefore, the collected (raw) data should be aggregated at national level into the total number of packages consumed (in the sample or MS) per VMP presentation per animal species or category" Concerning: lines 70-73 and lines 212-215 in the guidance. **Comment:** Switzerland will not be able to send the number of packages used per VMP presentation and pack size because our new database will not include prescription data on pack size level but on the VMP presentation (Sequenz-Number) **Proposed change:** We suggest to collect the total number of units per VMP presentation per animal species or category.	VMP presentation refers among others to a specific pack size. This has now been amended in the list of terms and abbreviations (Chapter 4). Furthermore, the option of providing data in the form of 'weight or volume of VMP' has now been added to the guidance.
6.	*Animal species/categories covered* In the draft guidance it is proposed that data could be collected on broilers and turkeys. These terms do not include breeding animals (parents, grandparents and elite birds) and therefore no data of the usage of antimicrobials in them is suggested to be sent to ESVAC nor reported by ESVAC. Finnish Food Safety Authority suggests that also the usage of antimicrobials in breeding birds should be included and data on use of antimicrobials in them should be provided by participating countries and reported by ESVAC. As written in the draft guidance the objective for collecting these data is to analyse these data in combination with data on the occurrence of antimicrobial resistance (AMR) in animal species in question, enable monitoring of patterns of antimicrobial use over time and the effect of implemented measures regarding prudent use of antimicrobials. It is	Thank you for your comments. The collection and reporting of data on antimicrobial use in breeding flocks is not currently envisaged for EMA purposes. However, and noting the importance of collecting data on the antimicrobial treatment of these flocks, these data can be collected at national level; it is recommended to analyse and report the data separately from data on antimicrobial use in broilers and/or fattening turkeys. The scope (Chapter 1.2) refers to the

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	also mentioned that data would allow for an integrated analysis with data on antimicrobial resistance in certain species and/or categories of animals and therefore, animal species and categories chosen are same as those in the antimicrobial resistance monitoring program. Poultry production is a highly specialized production system with different breeding generations. Antimicrobials are used in all the generations in poultry production. However, they are more often given to the breeding animals than to broilers and turkeys raised for slaughter. The usage of antimicrobials in breeding animals has effect on the resistance situation in broilers and turkeys. EFSA published Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals in 2011. As one of the risk factors contributing to the occurrence, emergence and spread of ESBL and/or AmpC-producing bacteria it is mentioned the dissemination of the bacteria in the poultry production chain through day-old grandparent chickens. Moreover, it is mentioned that some data indicate that the occurrence of these organisms in the different levels of the poultry production chain is the result of vertical transmission, local recirculation and selection. (EFSA 2011). The usage of antimicrobials in breeding animals has been found as a cause of emergence of AmpC producing E. coli in the broiler production chain in a countries with a low antimicrobial usage (Mo et al, 2014; Nilsson et al, 2014). Therefore, if only the data on the usage of antimicrobials in broilers and turkeys raised for slaughter will be collected, the data does not fully allow integrated analysis on the usage and resistance. If the use of antimicrobials in breeding animals is included the number of animals (denominator) can be problematic. At least in Finland and probably also in other EU member states the parents in broiler production are slaughtered and they are included in Eurostat numbers. One possibility to establish a denominator is to make an overall estimation of share of parent birds in poultry production in EU and use that as a denominator. The number parents is only a small fraction of the total amount of poultry and it should be known by the poultry industry. Also, one option could be that the data	potential adaptation of the guidance to other animal species at a later stage; this now includes a mention of other animal "categories (e.g. breeding poultry)". It should be acknowledged that breeding animals are often located in a few countries specialized in breeding animals, providing birds to several fattening populations in other countries. This complicates interpretation of results.

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	on usage in parents and birds for slaughter are collected separately but same denominator (number of slaughtered birds) could be used when the data are reported by ESVAC (mg [birds for slaughter]/PCU [slaughtered birds] and mg [parents]/PCU [slaughtered birds]). References EFSA. Scientific opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals. EFSA Journal 2011; 9: 2322. Mo SS, Norström M, Slettemeås JS, Lovland A, Urdahl AM, Sunde M. (2014). Emergence of AmpC-producing Escherichia coli in the broiler production chain in a country with a low antimicrobial usage profile. Veterinary Microbiology 171: 315-320. Nilsson O, Börjesson S, Landén A, Bengtsson B. (2014). Vertical transmission of Escherichia coli carrying plasmid-mediated AmpC (pAmpC) through the broiler production pyramid. Journal of Antimicorbial Chemotherapy 69: 1497-1500.	
6.	*Variables on antimicrobial use* According to the draft guidance data should be provided to EMA in the form of number of packages used per VMP presentation (i.e. pack size). Some countries may collect data as volume (ml/l) or weight (g/kg) of used antimicrobials especially when the data is collected at the farm level and they should aggregate the volumes or weights of used products into packages. This may cause unnecessary errors in calculations. Finnish Food Safety Authority suggests that the data could be provided also as volume or weight depending on the pharmaceutical form of product in question.	The option of providing data in the form of 'volume or weight of VMP' has now been added to the guidance.
7.	Background In March 2017, the European Medicines Agency (EMA) published a report that describes EMA's vision regarding the sector-level monitoring of antimicrobial use in food-producing animals. This document provides guidance to countries on the collection of antimicrobial	Thank you for your comments. It is acknowledged that the denominator that will be used to adjust and report the use data, i.e. the species

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	use data on the species or sector level. Species-level antimicrobial use data of participating countries would in the future be reported complimentary to sales data, which is annually reported by the "European Surveillance of Veterinary Antimicrobial Consumption" (ESVAC) project of EMA. The wider aim is that description of antimicrobial use data on the species or sector level makes use on the species level transparent and gives opportunities to interpret antimicrobial resistance data on the species level and compare or relate resistance data to antimicrobial use data. In this memo antimicrobial use indicators that are proposed in this document are discussed and compared with antimicrobial resistance data. To illustrate some methodological issues, available antibiotic usage data was used and the ESVAC methodology using population correction units (PCU) was applied and compared to another commonly used denominator that expresses live animal mass. Subsequently the association between use, calculated in different ways, and antimicrobial resistance was evaluated. <u>ESVAC indicators and other indicators commonly used</u> Three different indicators have been proposed by ESVAC to quantify antibiotic use in pigs, broilers, turkeys, veal production, dairy production and beef production: mg active substance, number of animal Defined Daily Doses (DDD_{VET}) and animal Defined Course Doses (DCD_{VET}) per population correction unit (PCU) for each species. The PCU is a combination of kilograms produced and kilograms livestock present for a species and is calculated on the basis of import, export, present and slaughtered animals. The PCU is also used as a denominator to compare antibiotic sales data across countries and species. A commonly used denominator is the average kilogram animal present (AKAP). This denominator represents the average animal weight at risk of being treated with antibiotics. The AKAP is used in many epidemiological studies and used for monitoring purposes in surveillance systems like the one present in the Netherlands for the calculation of the Defined Daily Dosages Animal ($DDDA_{NAT}$) by the Netherlands Veterinary	PCU, has certain limitations, as do other denominators. It is inevitable that there might be differences between the various surveillance and monitoring initiatives in the EU/EEA, not just in how and which data are collected but also in how results are presented. The guidance has the objective to inform on the data that would have to be provided to EMA and how these data would be used and presented. In order to provide (at a later stage) a data collection protocol that can be applied by all participating countries a pragmatic approach had to be taken regarding the data to be collected and provided. The decision on the denominator for the purpose of the guidance had to take into account the data that are available for establishing the denominator. These data need to be transparent, harmonised and standardised, as for example the data of Eurostat and TRACES. In case of a future data collection, results for participating countries will be reported as outlined in the guidance, ensuring the data presented are harmonised and standardised to the

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	Medicines Institute (SDa) or the Danish surveillance system DANMAP (DANMAP, 2015; Merle et al., 2012; SDa, 2017; Timmerman et al., 2006). Differences between the PCU and AKAP arise when the number of production cycles within a livestock sector does not equal 1. If multiple production cycles exist the PCU will be higher compared to the AKAP. Other differences relate to international standardized weights to account for between-country differences in animal weights, which may result in different standardized animal weights used by other (inter)national surveillance systems. However, this is a relatively marginal aspect compared to the first issue and harmonization on this aspect is required to be able to make comparisons across countries. This aspect will not be further discussed. Whether the denominator should reflect produced biomass (PCU) or present kilograms at risk for treatment (AKAP) is a more fundamental issue. Table 1 shows the differences between the PCU and AKAP denominator for 2012 to 2015 for the veal calf, broiler, cattle and pig sector using Dutch usage data as reported earlier in a series of SDa reports. In this example the AKAP is based on the Dutch standardized animal weights as used by the SDa. The factor 0.5 differences in the cattle sector are mainly caused by a difference in standard weight for dairy cattle, ESVAC uses 425 kg while SDa uses 600 kg. Broilers kept for meat production of regular breeds are approximately 6 weeks of age when slaughtered, corresponding to roughly 8 production cycles per year (Agrimatie, 2017). The number of production cycles per year largely corresponds to the differences between PCU and AKAP denominator. Pigs are slaughtered at the age of approximately 6 months, corresponding to roughly 2 production cycles per year (InfoNu, 2012). Differences between PCU and AKAP denominator, caused by differences in standard weight, account for a maximum reduction of 5% in PCU. Differences in PCU and AKAP denominator for pigs thus appear	extent possible. However, this does not preclude national reports adapted to local circumstances, e.g. by utilizing different indicators. Comparing antimicrobial resistance and use levels between different species should be done with care. For example, in poultry resistance can spread vertically from breeding birds down the production chain to fattener birds. Also, antimicrobials are mostly administered to dairy cows via parenteral or intramammary route. It may be questioned whether antimicrobials administered via these routes affect the gut flora, e.g. indicator *E. coli*, in the same manner as orally administered antimicrobials. Resistance is a complex phenomenon and cannot in all cases be explained linearly with use patterns. The JIACRA reports (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001863.jsp&mid=WC0b01ac0580c0fa1d) include some caveats on the analysis of antimicrobial resistance and sales of antimicrobials.

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to be mainly caused by the number of production cycles.

Veal calves are slaughtered at approximately six to twelve months, depending on the meat type. A weight of 140 kg is USED by ESVAC, while SDa uses 172 kg.

So, differences between PCU's and denominators based on present weight are most pronounced in high producing livestock sectors with short production cycles, such as the broiler sector. For instance, the difference between the PCU and AKAP denominator is roughly equal to the number of cycles per year.

Table 1: PCU and average kilogram animal present (AKAP) for 2012 to 2015, also given is the factor difference between the two measures.

		Broiler	Cattle	Pig	Veal calf
2012	**PCU**	496223492	792231175	1475179015	199135020
	AKAP[1]	43846300	1522500000	710688000	156602470
	Factor	11.3	0.5	2.1	1.3
2013	**PCU**	393048700	843717100	1473334000	203651000
	AKAP[1]	44242000	1532000000	710801800	159546550
	Factor	8.9	0.6	2.1	1.3
2014	**PCU**	414665914	842090285	1468740005	200610200
	AKAP[1]	47019800	1615000000	704937400	158827980
	Factor	8.8	0.5	2.1	1.3
2015	**PCU**	404254738	851327025	1660834835	203768600
	AKAP[1]	49107172	1680000000	706025000	156751000
	Factor	8.2	0.5	2.4	1.3

[1] Based on the standardized weights used by the SDa

Calculation of antimicrobial usage based on different methodologies

The average European veterinary dose per antimicrobial active substance, route of administration and livestock sector (DDD_{VET}) is determined based on Summary of Product

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	Characteristics (SPC) information on dosing collected from nine European Union Member States. To compare differences in calculated antibiotic usage between ESVAC and SDa, caused by differences in denominator, antibiotic usage was calculated in number of DDD_{VET}/PCU and DDD_{VET}/AKAP. Since both methods applied the number of ESVAC DDD_{VET} , this way differences exclusively caused by the denominator were assessed. PCU data was retrieved from the ESVAC database from 2012 to 2015. In remainder of this note 2015 antibiotic usage data are used to draw comparisons between the ESVAC and SDa antibiotic usage indicators. Supplementary table 1 shows the composition of the 2015 PCU for the different livestock sectors discussed in this note. Antimicrobial usage and resistance A clear change in antibiotic usage patterns was shown when using the PCU as denominator (figure 1) in comparison to both the DDD_{VET}/AKAP and $DDDA_{NAT}$. As mentioned before differences in denominator caused by differences in Dutch and European standardized weights are marginal and do not markedly change antibiotic usage patterns across sectors. It can thus be concluded that the different calculation methods for the denominator are the major cause of differences in observed antibiotic usage patterns. From an epidemiological point of view, the denominator should represent the kg population of a livestock sector that was at risk of being exposed over a set time period, for example one year. By using a production-based PCU the denominator becomes inflated for livestock sectors with multiple production cycles, while these animals were only exposed part of the year. Basically, in the PCU system each animal is considered being at risk for a full year (365 animal days) when the average weight is being used while that animal lived only part of that year (e.g. broiler 42 animal days). Using the PCU produced kilograms animal count as if they were potentially exposed during the whole year, which is not the case for livestock sectors with multiple production cycles. Dutch broilers are for example slaughtered at the age of 6 weeks and are thus only 6 weeks at risk of being treated with antibiotics instead of one year. The PCU currently described by	

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	ESVAC does not account for this shortened exposure time, therefore reported antibiotic usage is reduced in high producing livestock sectors by using the PCU as a denominator. The DDD_{VET}/PCU basically describes antibiotic usage per cycle. If for example antibiotic usage in the broiler sector is assessed in two countries (countries A and B) and the same amount of antibiotics is used in both countries, but country A has a more productive broiler sector (8 and 4 production cycles per year in respectively country A and B), reported antibiotic usage will be twice as in country B while the same amount of antibiotics was used. As illustrated in figure 1, which shows the prevalence of antibiotic resistant Escherichia coli strains and antibiotic usage in DDD_{VET}/PCU, DDD_{VET}/AKAP and $DDDA_{NAT}$ for the different livestock sectors, antibiotic resistance levels reported annually in the Netherlands by MARAN are the highest in the broiler sector, followed by the pig and veal calf sector for 2015. Reported antibiotic resistance levels are low for the dairy cattle sector. However, antibiotic usage expressed in DDD_{VET}/PCU is relatively low for the broiler, pig and dairy cattle sectors, while antibiotic usage is high for the veal farming sector. As a consequence, antibiotic usage expressed in DDD_{VET}/PCU does not reflect antibiotic resistance levels in the different livestock sectors. Similar results were found for 2013 and 2014 (see supplementary figures 1 and 2). Antibiotic usage in the broiler sector is 0.48 DDD_{VET}/PCU higher compared to the dairy cattle sector (1.99 for broilers and 1.51 for dairy cattle). However, antibiotic resistance levels in E. coli are 76.0% and 4.5% in the broiler and dairy cattle sector respectively. Antibiotic usage in the veal farming sector is 20.4 DDD_{VET}/PCU, which is more than ten times higher than antibiotic usage in the broiler sector (also in DDD_{VET}/PCU). However, E. coli strains resistant to at least one of the nine examined antibiotics are 1.8 times more prevalent in the broiler sector compared to the veal farming sector in 2015. Antibiotic usage patterns in DDD_{VET}/AKAP or $DDDA_{NAT}$ (DDDA/AKAP) more closely resemble antibiotic resistance levels across the different livestock sectors for 2015. <u>Conclusion</u>	

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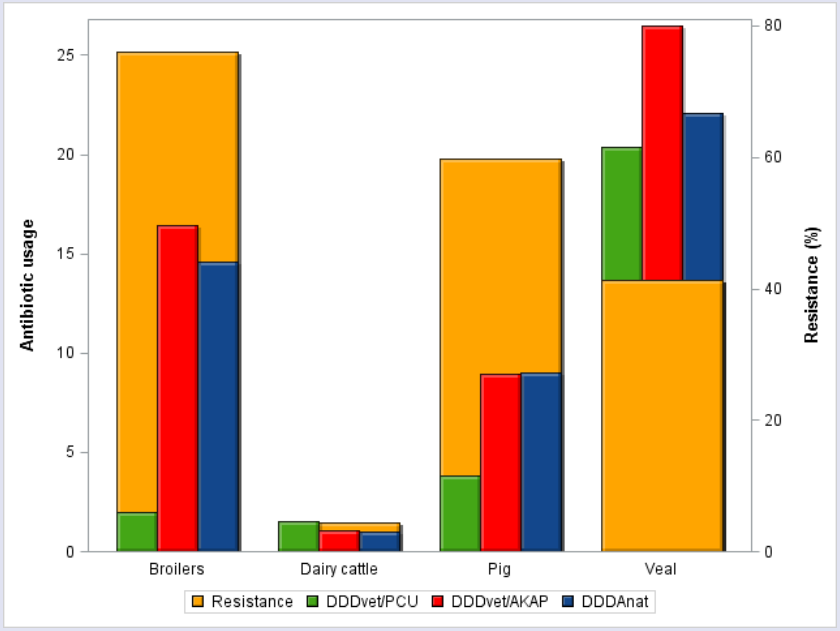
	This document illustrates that differences exist in antibiotic usage patterns when a denominator production-based is used compared to a denominator based on the average animal population at risk (animal time) of antibiotic treatment. The PCU does not represent the population at risk of being treated with antibiotics. The DDD_{VET}/PCU does not seem to reflect resistance patterns across livestock sectors. Trends between antibiotic usage among the average animal population at risk and resistance seems to be more comparable. This sheds doubts about the validity of the PCU as a measure of animal mass for antimicrobial usage monitoring. Using this approach will likely also affect associations such as explored in the JIACRA reports (EMA, 2017). Results from studies using the PCU will be at odds with results from studies using the more commonly used epidemiological metrics.  *Figure 1. A comparison of antibiotic usage with antibiotic resistance for 2015. Antibiotic usage was calculated using ESVAC methodology (DDDVET/PCU), ESVAC doses and AKAP*	

Stakeholder no.	General comment	Outcome
	as denominator (DDDVET/AKAP) and using SDa methodology (DDDANAT). Resistance percentages refer to the percentage of E. coli *isolates resistant to at least one of the testes antibiotics (MARAN, 2016).* References DANMAP, 2015. Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark. ISSN 1600-2032. EMA, 2017. Analysis of antimicrobial consumption and resistance ('JIACRA' reports). http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001863.jsp&mid=WC0b01ac0580c0fa1d. Retrieved September 6, 2017. InfoNu, 2012. Van Zeug tot Big tot Barg tot Karbonaadje. http://dier-en-natuur.infonu.nl/diversen/99940-van-zeug-tot-big-tot-barg-tot-karbonaadje.html. Retrieved August 28, 2017. MARAN, 2014. Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands in 2013. http://www.wur.nl/upload_mm/a/7/e/fb1c6b83-55ff-41c2-815f-15b40d1bb293_NethMap-MARAN2014.pdf. Retrieved September 4, 2017. MARAN, 2015. Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands in 2014. http://www.wur.nl/upload_mm/e/0/d/104f4c0c-1126-4b64-b55b-80bed717802a_NethmapMaran2015.pdf. Retrieved September 4, 2017. MARAN, 2016. Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands in 2015. http://www.wur.nl/upload_mm/9/b/0/e3377ca5-5c40-4bef-949c-1f52cc8b1522_NethmapMaran2016_A.pdf. Retrieved September 4, 2017. Merle, R., Hajek, P., Käsbohrer, A., Hegger-Gravenhorst, C., Mollenhauer, Y., Robanus, M., ... & Kreienbrock, L. (2012). Monitoring of antibiotic consumption in livestock: a German feasibility study. Preventive veterinary medicine, 104(1), 34-43. SDa, 2017. Het gebruik van antibiotica bij landbouwhuisdieren in 2016 - Trends,	

benchmarken bedrijven en dierenartsen. SDa/1151/2017.

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Appendix

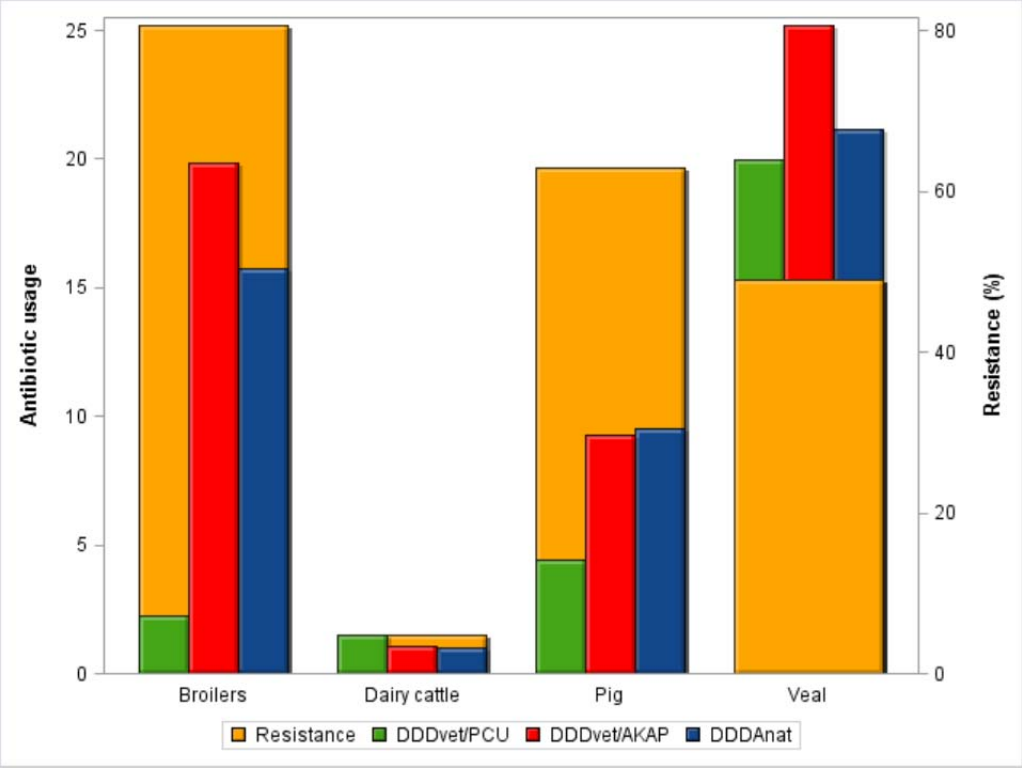
Supplementary table 1: PCU calculation per livestock sector using 2015 data.

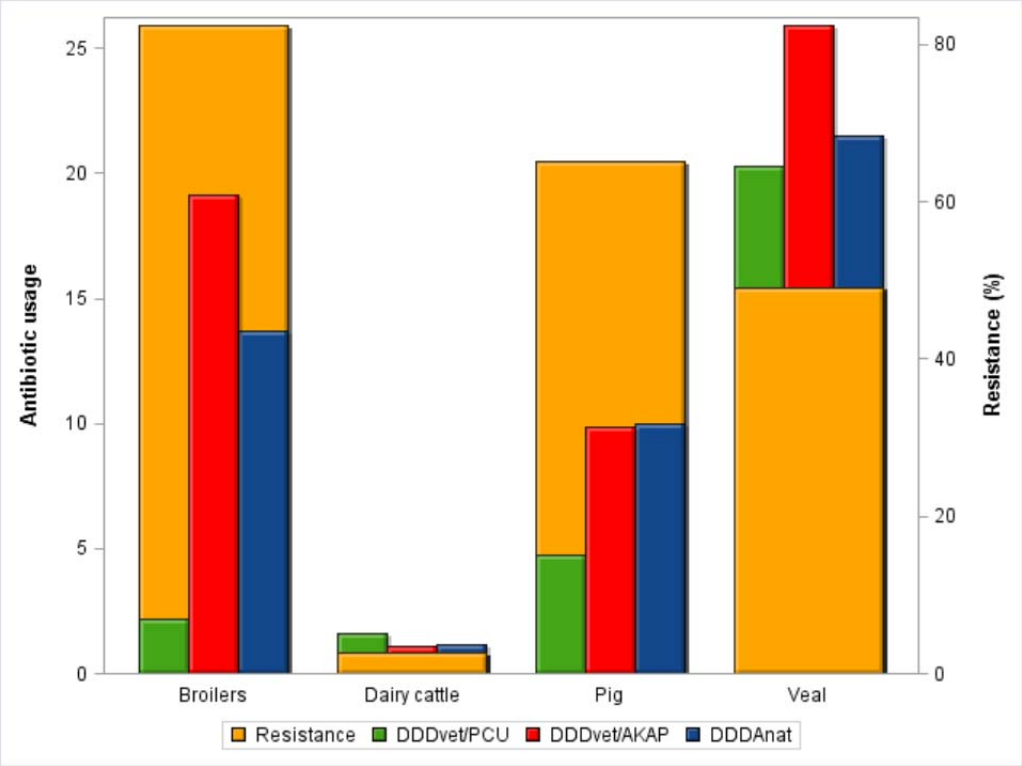
Sector	Category	Heads	Standard weight in kg	PCU
Broiler	Broiler	592145990	1	59214599
	Slaughtered Poultry – Import	245228539	1	24522853
	Slaughtered Poultry – Export	57337287	1	5733728
	Total	-	-	**40425473**
Cattle	Slaughtered Cow	429560	425	18256300
	Slaughtered Heifer	11680	200	233600
	Slaughtered Bullocks And Bulls	60150	425	2556375
	Slaughtered Bovine – Import	61316	425	2605930
	Slaughtered Bovine – Export	151743	425	6449077
	Fattening Bovine – Import	938375	140	13137250
	Fattening Bovine – Export	29145	140	408030
	Dairy Cow	1717000	425	72972500
	Total	-	-	**85132702**
Pig	Slaughtered Pig	15485070	65	100652955
	Slaughtered Pig – Import	437026	65	2840669
	Slaughtered Pig – Export	4168295	65	27093917

	Fattening Pig – Import	47205	25	118012
	Fattening Pig – Export	6409317	25	16023292
	Living Sow	1053000	240	25272000
	Total	-	-	**166083483**
Veal	Slaughtered Calves And Young Cattle	1455490	140	20376860
	Total	-	-	**20376860**

Supplementary table 2: Standard weights used by SDa for calculation of the $DDDA_{NAT}$.

Sector	Category	Standard weight in kg
Veal		172
Pig	Piglets (< 20 kg)	10
	Sows	220
	Meat pigs	70.2
	Other pigs	70
Broiler		1
Turkey		6
Cattle	Dairy cattle	600
	Other cattle	500
Meat rabbits	Weaned meat rabbits	1.8
	Doe	8.4

Stakeholder no.	General comment	Outcome
	 *Supplementary figure 1: A comparison of antibiotic usage with antibiotic resistance for 2014. Antibiotic usage was calculated using ESVAC methodology (DDD_{VET}/PCU), ESVAC doses and AKAP as denominator (DDD_{VET}/AKAP) and using SDa methodology ($DDDA_{NAT}$). Resistance percentages refer to the percentage of* E. coli *isolates resistant to at least one of the testes antibiotics (MARAN, 2015).*	

Stakeholder no.	General comment	Outcome
	 *Supplementary figure 2: A comparison of antibiotic usage with antibiotic resistance for 2013. Antibiotic usage was calculated using ESVAC methodology (DDD_{VET}/PCU), ESVAC doses and AKAP as denominator (DDD_{VET}/AKAP) and using SDa methodology ($DDDA_{NAT}$). Resistance percentages refer to the percentage of* E. coli *isolates resistant to at least one of the testes antibiotics (MARAN, 2014).*	
8.	We consider that it is important that information on the use of antibiotics within the EU is collected and presented in a structured and harmonized manner. A breakdown per animal species facilitates the follow-up of antibiotic resistance efforts in several ways.	Thank you for your comments. Comments noted.

Stakeholder no.	General comment	Outcome
	Not least, it is an important tool for following up the work for a restrained and responsible use of antibiotics. It is therefore important that the coming data collection systems can provide harmonized and comparable information on the use of antimicrobial agents in the EU. We find it appropriate that the reporting system is adapted to the monitoring and reporting of antibiotic resistance in zoonotic and commensal bacteria according to Commission Decision CID 2013/652 / EU.	
9.	The FESASS welcomes with great interest this proposal because there is an important need to obtain more accurate and comparable data on antimicrobial use in EU. But this need concerns both human and animal health. Indeed, the fight against AMR must be conducted within the framework of a global and "one health" approach. For us the registration of antimicrobial uses in animal health should be proportionate to the registration of antimicrobial uses in human health giving a particular attention to the uses in hospital.	Thank you for your comments. Comment noted; further information on the collection of data on antimicrobial use in humans (ECDC's ESAC-Net) can be found here: https://ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/esac-net.
10.	FVE very much welcomes this guidance on provision of data on antimicrobial use by animal species from national data collection systems. The guidance is timely as we see that more and more countries start to monitor, in addition to antimicrobial sales, antimicrobial use by (sub) species. It is crucial to harmonise the way this is done by following the same ATCvet in order for the data to be useable and comparable on a European level. Collecting antimicrobial use data per species allows to better prioritise actions to reduce AMR. 1. We support a data collection period of 1 calendar year. 2. We strongly prefer an automatic continuous 'census model' above the 'sample survey model'. An automated continuous census model has the benefits of being more reliable, covering most of the animal production sector, has higher set-up cost but lower maintenance cost, allows to monitor patterns of use over time and after implementing	Thank you for your comments. - Point 1: Comment noted. - Point 2: Comment noted. - Point 3: Comment noted. A census model would allow for the use of data from Eurostat and TRACES, which would fulfil the criteria mentioned. - Point 4: Comment noted. - Point 5: Comment noted. - Point 6: Comment noted. However,

Stakeholder no.	General comment	Outcome
	measures, allows benchmarking between farms and can be used to pay extra attention to farms using above the average amount (or under- as good examples). 3. Special attention needs to be paid to making sure the animal population data is accurate, especially seen that animal productions is more and more European, with at times animals born in one Member State, raised in another Member State and slaughtered in yet another Member State. A simple and practical collection system needs to be used, with not too much bureaucracy for all involved. 4. With the sample approach, one has to be very careful as we see that antimicrobial use within the same species and country can vary greatly from farm to farm. It also does not give a consistent picture, and needs ad-hoc collection each time. 5. Special attention is needed to ensure reliable animal population estimates. 6. At some places, the guidance documents could give more 'guidance', e.g. on which species to prioritise, on the frequency of data collection, etc. 7. It would also be useful to add a chapter on how ESVAC plans to publicise the data. Some details are specified in line 267 to 272 but no details e.g. on the frequency, whether these data will be included into the annual ESVAC reports, etc.	one of the objectives of the guidance is to inform which data may need to be provided to EMA if/when the revised EU regulation on VMPs comes into force. As it is currently unknown which exact requirements will be included in the final revised regulation, the guidance is informative. Exact and/or binding requirements might be included in the delegating/implementing acts. - Point 7: Comment noted. The frequency of reporting would depend on the frequency with which data would be provided to EMA. It is currently envisaged that the data by species would be reported separately from the ESVAC sales reports.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
4-5	4.	**Comment:** Data will be collected from countries not from national systems. (National systems should be changed to countries throughout the document where it is used in the same context). It can also be questioned if sample surveys can be characterized as systems. **Proposed change:** Guideline for surveillance of antimicrobial use data by animal species at EU/EEA level and how to obtain these data at national level	The title of the guidance has been changed to "Guidance on collection and provision of national data on antimicrobial use by animal species/categories"
46-49	4.	**Comment:** It reads: *"This guidance document defines the type and format of data to be provided to the European Medicines Agency (EMA) from national systems collecting antimicrobial use data by animal species for those European Union/European Economic Area Member States (EU/EEA MSs) wanting to provide such data to EMA".* 1. In the text that follows it is not data type that are described but partly variables. (Data type are e.g. prescription data, health record data) 2. See comments above. The guidance does not describe the format but variables etc. for submitting data to EMA in the future. Format is discussed in context of setting up system for collection of data at national level (e.g. Chapter 2.1. and Chapter 3). 3. See previous comments to *"…….wanting to"* **Proposed change:**" This document defines which antimicrobials should be included in the data collection, which species/production categories for which the data should be collected, time schedule for collection of the data and variables for the antimicrobial use data to be provided to the European Medicines Agency	The sentence has been modified taking into account the comment received. However, the guidance document is not intended to act as a strict guidance on the model for collecting data at a national level. This should be decided at the local level as it is recommended to be adapted to the local situation (e.g. distribution of medicines, legislation, resources).

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		(EMA) And add: "Furthermore it provides guidelines on how to obtain the data on antimicrobial use at national level"	
47 151	10.	**Comment:** add category, idem line 151, etc. Also please consider if age is included in category, if not add age. 'by animal species/age/category'. **Proposed change:** 'collecting antimicrobial use data by animal species/category for those European Union/European Economic Area Member States (EU/EEA MSs)'.	This has been added at the appropriate places. Depending on the species age is implicitly included; please refer to Annex 2 table 5 for the definitions.
49-50	3.	**Comment:** The Question and Answer document (EMA/716249/2016) does not have a structure which gives clear indications for the rationale behind the decisions taken. **Proposed change:** Please integrate the explanations into the main document.	Headings have been added to group the questions and answers according to the chapters of the guidance. The explanations included in the Q&A document are considered to be too detailed or outside the scope for inclusion in the guidance document.
51-53	10.	**Comment:** suggesting to underline that while now data collection is not mandatory, almost all member states report the data to ESVAC and that with the Revision of the legislation the aim is to make it mandatory. **Proposed change:** … monitoring of antimicrobial use is not mandatory at EU/EFSA level, but nevertheless almost all EU/EFTA countries perform monitoring and share the data with ESVAC. Mandatory monitoring is also suggested in the revision of the veterinary medicines legislation, currently under discussion.	A sentence has been added to the text. At this time, no further reference to the revision of the EU regulation can be made.
54-55	4.	**Comment:** "…the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) team". Suggest this is not appropriate in an EMA guidance.	This is amended throughout the document.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		Proposed change: Suggest changed to EMA or the Agency. (Applies also to elsewhere in the document where "ESVAC team" is used in the same context).	
54-58	3.	**Comment:** The document does not really specify how the objective of reliable, harmonised and standardised data on antimicrobial use by animal species/category in each reporting MS will be achieved. **Proposed change:** Please define clearly the minimal requirements for data to be reported and how the data quality will be validated.	It is believed this has been sufficiently addressed in Chapter 2.5 and Annex 2 Chapter 3.
62-67	4.	**Comment:** See comments to Chapter 2 on terms used for animal species/production categories and in general comments about the schedule.	See previous comments.
64-65	10.	**Comment:** Data to be collected at this moment involve the ATCvet groups and sufonamides. It should be recognised that in the future, it could be necessary/beneficial to collect data of other veterinary medicinal products. **Proposed change:** …Data collection by species should involve at least the same ….	Text is amended.
70-73	3.	**Comment:** For data management purposes and to ensure completeness of the data, antimicrobial use data would have to be provided to EMA by use of a template developed and provided by the ESVAC team, in the form of number of packages used per veterinary medicinal product (VMP) presentation per animal species/category in the MS. **Proposed change:** There is no rationale given why data have to be provided by packages, but this introduces bias into the data collection. To ensure consistency with national approaches the amount of raw antimicrobial ingredients should be	See previous comment.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		the basis for data collection.	
73-77	3.	**Comment:** This summary reflects one of the major problems with the draft proposal. It is quite unclear how the population under risk will be estimated and how different livestock production systems will be handled. The same problem as with the sales data system will arise, that for some countries biased denominator data will be used. **Proposed change:** There should be an assessment of the impact of the different procedures to estimate the denominator data. Based on that a clearly described procedure should be established which ensures comparability of data without having negative impact on some countries.	Comment noted. It was considered that a pragmatic approach has to be applied when a supranational protocol is established. The data to be collected on the animal population ideally should originate from validated and publicly available sources. Together with the prerequisite that those data are harmonised and standardised between countries, this limits the sources of data that can be used. An explanation on how the denominator will be established is given in Annex 2, Chapter 2.2.2. but has been further clarified.
81-84	3.	**Comment:** As summarised here the indicators used will be based on biomass, as already the sales data analysis. As now antimicrobial use by animal species will be compared, a clear description of the limitations of these indicators should be given. **Proposed change:** A chapter on the limitations of interpretation of these indicators by animal species should be included.	This is considered outside the scope of this guidance document.
101-106	3.	**Comment:** To achieve these objectives, first of all a procedure has to be implemented to collect comparable data on animal species level. Only then, it is scientifically acceptable to perform the analyses as suggested.	This is referred to in Annex 2, Chapter 3. See also previous comments.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		Proposed change: Include a chapter which clearly specifies how data quality and comparability will be ensured. It should be clarified that only data fulfilling the standards set will be included in any assessment.	
102	1.	**Comment:** Good to measure impact of use on levels of AMR but should also be monitoring impact on animal welfare	This is considered outside the scope of the guidance document.
107-114	3.	**Comment:** As already mentioned in previous comments the proposal is not sufficiently precise in the requirements for data to be collected. It focuses on collection of data which are not standardised. **Proposed change:** See general comment on the stepwise approach to be taken and previous comments on data quality.	Comment noted. See previous comments.
137 - 138	4.	**Comment:** See previous comments. **Proposed change:** To define which data on antimicrobial use by animal species/production categories to be provided to EMA from EU/EEA countries.	Sentence has been amended.
139	4.	**Comment:** See previous comment. **Proposed change (if any):** Suggest to delete.	Not agreed. The bullet point is kept.
140	4.	**Comment:** It is unclear how EMA through this guidance would ensure reliability and it is not necessary to include it in this guidance. **Proposed change:** Suggests to delete reliable.	The term has been deleted.
145-147	4.	**Comment:** It reads "*is not mandatory, but details how the ESVAC activity proposes the collection of antimicrobial use data by species at EU/EEA level, without indicating for which animal categories data should be collected*". Similar to ESVAC team, the term ESVAC activity should be avoided	The term ESVAC activity has been replaced by EMA. The second half of the bullet point is deleted.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		The document proposes for which animal species/production categories for which the data should be provided. See also previous comments. **Proposed change:** details which data are recommended to be collected on antimicrobial use by animal species/production categories at EU/EEA level	
153-155 411-432	9.	**Comment:** Yes it is important to collect the sales data as close as possible of the farmer. For us, taking in account of the heterogeneity of antimicrobial marketing and distribution systems between Members States, and because it will not be possible to easily aggregate data directly from the farm level, we propose to collect the data from all the "authorised to sell persons". This approach would enable to avoid the risk of having multiple observations on the same treatment (mentioned line 427-428).	Comment noted. We believe that these persons are included under "…veterinarians, pharmacies, etc.)". However, the guidance refers to use data and is not intended to replace the ongoing collection of sales data.
154-155	4.	**Comment:** "*… but data provided to EMA would be aggregated at national level for analysis and reporting by animal species (or category) by EMA*". Suggest that this does not fit in here. **Proposed change:** Suggest to delete.	It is considered to be necessary to distinguish between the raw data which are collected by the country (nationally) and the aggregated data which would be provided to EMA.
156-157 180-194	9.	**Comment:** We regret that the antimicrobial uses in pet animals are not targeted at this first stage. They pose significant risk because these animals live longer than farm animals (so they can easily develop AMR) and they live closer and continuously of humans.	Comment noted. At the moment it is difficult to report data on antimicrobial use in companion animals as there are no reliable data publicly available on the size of the populations of companion animals in the EU/EEA MSs.
158-160	9.	**Comment:** a pragmatic approach will also be necessary in order to allow enough time to the Member States to develop simple, efficient and effective data	Comment noted.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		collection systems (conception, availability of technical means and implementation).	
158-160	4.	**Comment:** It reads "*is intended to be pragmatic to ensure that the required data can be provided by all EU/EEA MSs wanting to do so and, at the same time, to ensure that those data are sufficiently accurate to meet the objectives for which they are provided to EMA.*" It is suggested that "*intended to be pragmatic*" is not an appropriate phasing in a guidance document. It's a question about feasibility (resources). **Proposed change:** Suggest deleting this bullet point.	The bullet point is kept. In this case, pragmatic encompasses the balance between feasibility and reliability. Feasibility can only be determined by the MSs (according to resources, etc.). It is also noted that "pragmatic" is a term used in other EMA guidance.
161-163	9.	**Comment:** As the proposal of new EU regulation on VMP is still in discussion, it would be possible to have to review this guidance in a close future if the legal requirements would be higher. In this perspective, this guidance has to plan the possibility of further consultations.	Comment noted. As for other guidance there might be a need for revision after a few years.
177-178	4.	**Comment:** It reads "*A list of variables included in the tentative ESVAC species templates can be found in Annex 5*". NFSA has not identified that any tentative template is available. Also there are two lists in Annex 5 – numerator and denominator. **Proposed change:** Variables on antimicrobial use by animal species and on animal population data for sample surveys to be provided to EMA are listed in Annex 5. (Text Table 9 and 10: should be revised accordingly)	The tentative template was not provided with the draft guidance. The text has been revised.
181-183	3.	**Comment:** In this paragraph no clear description is given how exactly animal species and categories will be defined. A reference to Commission Implementing Decision (CID 2013/652/EU) is misleading as there mainly slaughtered animals are addressed. **Proposed change:** Include a chapter with precise definitions for each animal	The CID to which reference is made is the regulation on AMR monitoring. Annex 2 Chapter 2.2.2. contains in table 5 the definitions of the animal species and categories for which data

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		species and categories to ensure that Member state have clear guidance on how to report their data. In addition, specify whether only poultry which falls under the European salmonella control programs should be included or all poultry kept in a country. Similarly, specify how to deal with a situation if only a subset of all animals kept in a country are subject for data collection.	would have to be provided. The abovementioned table also specifies that all chickens and turkeys slaughtered or traded within the EU/EEA countries need to be included. Annex 4 deals with establishing the sample in case of a survey on a subset of the total animal population in a country.
190-191	4.	**Comment:** In case dairy cattle and beef cattle are kept in the guidance: for the purpose of consistency it is suggested to replace dairy production and beef production with the categories used in Table 4 (in line 649 it reads dairy cattle and beef cattle). **Proposed change:** In addition the guideline covers data collection for the following bovine animals Dairy cattle Beef cattle (Cows, heifers, bullocks and bulls)	The text has been amended.
192	10.	**Comment:** On a later stage, data collection should also be foreseen for companion animals, rabbit production, aquaculture and any other animals produced over a certain threshold in Member States. Already several Member States collect data on the antimicrobial use in Companion Animals such as dogs and cats as the risk for transfer of resistance is high due to them living in close contact with their owners.	A reference to the potential inclusion of more animal species in the data collection is made in Chapter 1.2 and Annex 2. Countries can include more species in the national data collection, but those data would not have to be provided to EMA.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		Proposed change: To include sentence: 'On a later stage, guidance on data collection should also be foreseen for companion animals, rabbit production, aquaculture and any other animals produced over a certain threshold in Member States.'	
192-194	4.	**Comment:** See previous comment. **Proposed change:** Suggest to delete.	See previous comment.
201	1.	**Comment:** We agree data collection period should cover one year.	Comment noted.
202-209	10.	**Comment:** This paragraph does not give much of guidance, saying MS could submit yearly or bi-yearly in line with 2013/652/EU, or as they prefer. Would it not be better to give as guidance a preference for one option (e.g. yearly) and the other possibilities as back-up options?	See previous comments.
204	1.	**Comment:** For comparative purposes it would be best to have a single reporting period i.e. a calendar year for all MS and all species.	Comment noted.
204 - 206	4.	**Comment:** It reads "*Data could be provided to EMA on an annual basis or for each species on alternating years, following the frequency and schedule of the AMR sampling in accordance with the CID on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (CID 2013/652/EU).*" See general comments. **Proposed change:** It is proposed to collect antimicrobial use data for each animal species/production category following the frequency and schedule of the AMR sampling in accordance with the CID on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (CID 2013/652/EU)	See previous comments.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
207-209	4.	**Comment:** See general comments. **Proposed change:** Suggest to delete this sentence.	See previous comments.
211-216 800-802	8.	**Comment:** We consider that the amount of antimicrobial agents calculated from actual treatments according to the veterinary prescription (dose, frequency and duration) generally gives the most accurate amount. If information is collected in this way, calculation to a corresponding number of packages could lead to an extra administrative burden for the MS. In addition, this type of reporting system can cause an error when transforming of the actual (administered) amount to the total use in packages and package size. **Proposed change:** an option to report amounts sold or used in mL or mg should be given, as alternative to number of packages and package size.	The option of providing data in the form of 'weight or volume of VMP' has now been added to the guidance.
212-214	3.	**Comment:** Data should be provided to EMA by web-based delivery in the form of number of packages used per VMP presentation (i.e. pack size) in the MS per animal species/categories during the data collection period. **Proposed change:** Data should be provided in kg of the antimicrobial substance.	The option of providing data in the form of 'weight or volume of VMP' has now been added to the guidance. See also previous comments.
212-215	9.	**Comment:** The use of "number of packages" must be clarified because more frequently the prescription are made by mg and not by packages. The collect and the use of this kind of data do not seem so easy. It could be necessary to verify which kind of prescription is more frequently used in Member States.	The option of providing data in the form of 'weight or volume of VMP' has now been added to the guidance.
212-221 Table 2	4.	**Comment:** Lines 212-216 does not fit to heading as it addresses data submission to EMA and what to include in the data (unlicensed products). Table 2 is a shortlist of Table 9 and this should be explained.	The heading is moved to the appropriate position. The text has been amended.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		Proposed change: Lines 217-218: The variables needed for each VMP presentation or medicated feed used in the specific animal species/production category in order to calculate the amounts used in tonnes of active ingredients are shown in Table 2. A complete list of variables on antimicrobial use can be found in Annex 5, Figure 9 (suggest to delete country, year and species from the table) Table 2. The variables needed for each VMP presentation or medicated feed used in the specific animal species/production category by country and year to calculate the amounts used in tonnes of active ingredients	
216	1.	**Comment:** We are surprised by the reference to the use of unlicensed products – would such use be legal?	The term is now clarified in the text.
216	10.	**Comment:** 'This should also include unlicensed products.' Would be worth detailing this paragraph on what is meant exactly. Is different for using products under the cascade, than for using totally unlicensed antimicrobials for a specific species or even for animals (e.g. a human antimicrobial not licensed for animals). How about the ATCvet code? **Proposed change:** Explain sentence.	The term is now clarified in the text.
223-226	3.	**Comment:** For EMA purposes, the denominator with which use data can be adjusted (i.e. taking into account the animal population at risk of being treated with antimicrobial agents) will be calculated from a combination of the number of animals slaughtered and live animals present during the data collection period in a MS or on a sample of farms, multiplied by standardised weights. **Proposed change:** Please specify how denominator data will be calculated.	Please refer to Annex 2 Chapter 2.2.2. where an example of the calculation now has been included in the text.
223-234	4.	**Comment:** It seems like the suggested denominator is the same as PCU used to	The PCU is traditionally used to report

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Table 3		report ESVAC sales data. If that is the case it is suggested to revise the text accordingly and refer to annexes. **Proposed change:** The denominator proposed to report antimicrobial use data covering the whole population in the MS for the animal species/species category under surveillance is the population correction unit (PCU) used to report ESVAC sales data (refer to annex and Chapter on indicators). Of note is that data to calculate PCU for the species/species category under surveillance are already collected for the reporting of the sales data at EU/EEA level and thus the MSs would not have to provide these. When antimicrobial use data are collected through sample surveys (representative sampling), animal population data to calculate the PCU for the population under surveillance will have to be provided to EMA (See Annex 2, chapter 2.2.2). The data to be collected is described in Table 3.	data on overall national sales of veterinary antimicrobials, and is a composite variable covering multiple animal species, representing the animal demographics in a country. Since the guidance is intended for collection of data by species it was in the first instance decided to use a different term to distinguish between overall sales data and use data by species, also due to the slight difference in calculation. However, considering the widespread use of the term 'PCU' and that it refers to 'standardised weight at treatment' whereas 'biomass' traditionally refers to 'live or slaughter weight', it is decided to use the term 'PCU' in the guidance. A clarification has been included in the guidance.
226-230	3.	**Comment:** In this paragraph it remains unclear how the population under risk is exactly estimated. Transparency and a detailed assessment of the approach is very important to ensure comparability between systems and a reliable assessment of the magnitude of antimicrobial use. For example, from the description in Table 3, it is not clear whether some animals are considered repeatedly. For example, dairy cows are listed twice in	This has now been further clarified in Annex 2 Chapter 2.2.2. For dairy production only live dairy cows are included; for beef production only slaughtered cows (dairy and non-dairy) are included.

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		the denominator, for dairy production and for beef production. **Proposed change:** Include a chapter with a clear description how denominator will be calculated. Table 4 in Annex 1 does not give the necessary information.	
235-238 Table 3	4.	**Comment:** Table text should only include what is shown in the table. 2nd column does not describe any variables used to do any calculations, only categories. The table as such: For the purpose of consistency Veal production should be Bovine animals slaughtered below one year of age (as in line 187). Suggest deleting "live" for breeding sows and dairy cows as obviously they are alive. (applies also elsewhere throughout the document when used in the same context) **Proposed change:** Table 3. Data to be provided to EMA on numbers for the various animal species/categories when the data on antimicrobial use are collected by sample survey. Heading 2nd column: Suggest it should be Categories (table text explain when such data have to be provided).	The table heading and heading of the second column are adapted as well as the names of the variables for clarification purposes. However, 'live' has been retained for clarity.
238	10.	**Comment:** Table: suggest to include distinction between calves and young cattle. **Proposed change:** … Calves (less than 8 months) sent to slaughter Young cattle (between 8 and 12 months old) sent to slaughter …	This is added to the table.
238	10.	**Comment:** Table – do we need to include the animals that were sent to the rendering plant or culled in disease control measures or died e.g. in a stable burn or another calamity? Guess especially in the case of an outbreak of an notifiable disease numbers could be high and these animals will also have been treated.	These data are assumed not to be included in the Eurostat data.
244-249	3.	**Comment:** As already commented previously, these indicators are very rough	It is acknowledged that the estimated

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		and depend very much on the approach taken to calculate the biomass which will give a misleading picture for some animal species and livestock production structures. **Proposed change:** As already described in the general comment, there should a requirement for EMA, to assess for each report also the impact of the different livestock structures on the magnitude of the indicators. This critical assessment should be part of the development of the data collection system and included into the report and the communication strategy.	biomass is a proxy and not an exact representation of the animal population at risk.
257-265	3.	**Comment:** This paragraph already highlights that there are major gaps in the implementation of appropriate data collection systems. **Proposed change:** As already stated in the general comment, a stepwise approach should be developed and described here. Focus should be laid here to describe the details for the first step.	See previous comments.
258-260	4.	**Comment:** It reads "*DDDvet and DCDvet are technical units of measurement that take into account differences in dosing between species and substances (i.e. differences in potency of substances).*" Formulation is missing in the definition. Potency is challenging to define so it is suggested deleting it. **Proposed change:** DDDvet and DCDvet are technical units of measurement that take into account differences in dosing between the antimicrobial substances, formulations animal species.	Text is amended.
259-260	4.	**Comment:** It reads "*… which may lead to systematic differences between animal species/categories and between MSs*." **Proposed change:** NFSA do not understand the link between this and the text that follows and suggests that this part of the sentence to be deleted.	The text has been amended to clarify this link.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
260-265	4.	**Comment:** The purpose of collecting these data should be mentioned first **Proposed change:** For the interpretation of the data on use of antimicrobials by species/species categories information of the characteristics of the data collection system is important. Therefore, it is proposed that countries complete a questionnaire on the characteristics of the national data collection system.	The text is amended.
260	4.	**Proposed change:** Pharmacists should be pharmacies.	Change is made.
273-276	4.	**Comment:** It reads "*It is necessary that the authorities providing data to EMA would have access to the raw data or would be able to work with the raw data holders for e.g. validation purposes or data quality control. Arrangements and provisions would have to be made between authorities and data holders to ensure for example the protection of (commercially) confidential information*". Firstly, it does not fit with the chapter heading. Secondly, what is meant by having access to raw data? Raw data is defined in lines 305-308 and this is what is collected in Norway by NFSA. **Proposed change:** Suggest to delete the paragraph.	It is believed it needs to be highlighted that even though EMA does not request detailed data, the authorities may need to have access to those data. Therefore provisions need to be in place to ensure confidentiality, etc. However, the paragraph has been rephrased to clarify this further.
273-276	3.	**Comment:** in this paragraph, data validation and data quality control by the authorities providing the data is mentioned. But up to now there are no requirements for data validation and quality control given in the document. **Proposed change:** As already stated in the general comments, details on data validation and data quality should be developed. This should give clear indications what level of information should be available for authorities providing the data. Only if this in clarified, next steps can be taken.	Comment noted. It is believed that this depends mainly on the local circumstances, and therefore should be decided by the local authorities. However, Annex 2 Chapter 3 is dedicated to this subject.
278-314	3.	**Comment:** In this chapter, important definitions are missing. **Proposed change:** In this section each animal population category for which	Comment noted. It is believed that Annex 2 Table 4 provides sufficient

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		antimicrobial use data might be reported should be defined precisely. As national systems are different, definition of several suitable subcategories might be necessary.	details.
279-312	4.	**Comment:** To include three terms what actually seems to be the same is confusing: Biomass, Denominator and PCU. It should be made clear in the text (see comments to lines 223-234 above) that (if it is) PCU is proposed to be used as denominator and then define it in Chapter 4. Since EMA is the owner of this document EMA should not be included in the list of terms. It reads: "Indicator: proxy to describe use of antimicrobials (usually in the form of quantity per unit of denominator)". It is correct that it is a proxy but it should not be include it in a definition as phrased here. NFSA has not identified any definition for indicator in the context of reporting antimicrobial use data and as it is clearly explained in Chapter 3 what it is and it seems not necessary to include it in Chapter 4. The definition of Presentation is not correct and should be VMP presentation. To include a definition of a farm seems unnecessary. **Proposed change:** Suggest deleting Biomass, Denominator, EMA, Farm and Raw data from the list. VMP presentation: product name, form, strength and pack size of a VMP.	Biomass and denominator have been deleted. The term 'farm' has been kept as it is to clarify that this also can be referred to as holding. 'Raw data' has been maintained in the list as it is believed to be important to distinguish between the data that are collected (i.e. the raw data) and the data that are provided to EMA. The other terms mentioned have been amended as per the proposal.
312-313	3.	**Comment:** Currently, several types of data are summaried as "Use": prescribed, administered, purchased or delivered amount of antimicrobials to certain animal species on a farm/holding.	Comment noted. It is acknowledged that different types of data and data sources can be utilized to provide

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		Proposed change: This definition gives the impression, that quite different types of data should be handled in the same way which introduces major bias when data compared between countries.	information on use of antimicrobials by animal species/category. However, due to the supranational character of the intended data collection a pragmatic approach is believed to be needed. This is also (shortly) discussed in Chapter 3.2.
326-514	3.	**Comment:** The role of Annex 1 is not clear. If these are further details to be considered when setting up a system, the details should be clearly specified and integrated into the main text. If it is just an example for countries having no system in place without any binding role, this should be clearly specified too. **Proposed change:** Include those elements which should be followed in the first step by all countries into the main text, and highlight that the remaining text is an example without any binding role. Otherwise, delete the annex.	The main body of the guidance highlights the data that would need to be provided to EMA. As mentioned in Chapter 2, the Annexes are intended to provide information that can be used by authorities wishing to set up a system collecting data on antimicrobial use by species. A sentence clarifying this is now included in the Annex.
337-342	4.	**Comment:** Repetition of text provided in Chapter 2. **Proposed change:** Suggest to delete.	Deleted.
Line 343	10.	**Comment:** Should this list not be consistent with the table on line 238?	Comment noted. This list refers to those species included in the AMR monitoring, whereas Table 3 includes the variables to be collected in case of a sample survey. This has been clarified.
349-350	10.	**Comment:** For Member States wanting to do a phased approach, would it not	Comment noted. However, considering

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		give them guidance for ESVAC to suggest priority species based on resistance levels e.g. to start with broilers, follow by pigs, etc. **Proposed change:** Suggest priority species for a phased approach.	the lack of specific legal requirements for collection of farm level data at EU level, the guidance document is not intended to make binding recommendations on e.g. for which species to collect data. The prioritisation of animal species may differ between countries.
356-357	4.	**Comment:** It reads *".. such as 3rd-4th generation cephalosporins in intramammary preparations or injectable products."* Either all or none of the priority CIA classes/subclasses should be mentioned or preferably the AMEG categories. **Proposed change:** Suggest to delete.	The substance examples have been deleted and the AMEG categorization is mentioned.
389-406	8.	**Comment:** We consider that collection and reporting of data under the "sample survey" model limits the ability to make comparative analyzes in the future. Instead, we believe that the "census" data collection model is a more appropriate system for collecting data and reporting the use of antimicrobial agents.	Comment noted.
390 – 406	10.	**Comment:** Please insert a sentence about the need for simplicity to collect these data. In order for the system to be maintainable and practical, the system has to be automated and require little bureaucracy e.g. automatic collection via the farm or veterinary practice management system. Nobody likes to fill in a lot of papers which come on top of their normal work. **Proposed extra sentence:** A data collection model need to be found which can collect these data in a practical and automated way, without the need to fill in a lot of forms.	A modified sentence is added.

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412-422	4.	**Comment:** It does not fit with the heading. **Proposed change:** Delete here and include it in a separate chapter.	The paragraph has been moved.
416	10.	**Proposed change:** 'Furthermore, to establish the collection of complete, reliable data on all events of antimicrobial use per animal species/category in a country, it should be ensured that data on any use of medicated feed containing a premix of veterinary medicine/drinking water/milk replacer (containing antimicrobial substances) is included in the data collection as well.'	The sentence has been modified to clarify its meaning.
464-467	9.	**Comment:** The use of standardised weight is required and completely justified. But these indicators must be adapted to the national production specificities which can differ significantly between Member States (e.g. pig productions). Therefore we strongly recommend to use national standardised weight rather than European ones.	Comment noted. It is acknowledged that animal weights may differ substantially between countries; however, in order to report standardised and harmonised data by EMA, European standardised weights will be applied.
468-470 Table 4	4.	**Comment:** In the Animal species and category column it reads e.g. Pigs for slaughter while in the Definition column it reads Slaughtered. NFSA understands that the data that will be used to calculate PCU are number of slaughtered animals and suggest changing Pigs for slaughter to Slaughtered pigs in order to avoid confusion. This is suggested for the other parallel cases. Furthermore, it reads e.g. "Pigs imported /exported certified as fattening". TRACES issues health certificates, which are obligatory for all animals crossing any border; the animals as not certified for fattening as such. **Proposed change:** Pigs imported /exported for slaughter	Text has been adapted.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		Pigs imported /exported for fattening The proposal is in line with terms used in the ESVAC sales report. This is also suggested to be rephrased for the other similar cases.	
515-608	4.	**Proposed change (if any):** Suggest this chapter as Annex 1 as it describes aims for collecting use data.	Annex is moved.
515-609	3.	**Comment:** In the Annex, there should be a clear separation on the possible benefits which are in line with the objectives of the proposed data collection systems and those which could be considered in the future. **Proposed change:** Use and Benefits of the proposed system should be included in the main text where the objectives of the system are described. Future developments can be described here, but should be better described under a topic 'limitations' of the current approach.	The scope of the Annex is wider than the scope of the guidance document. The use and benefits were conceived as arguments for collecting these data, and therefore stakeholders requested them to be included. Future developments are not necessarily considered to mean current limitations.
557	10.	**Proposed change:** 'Off label use with regard to the amount to be administered (e.g. underdosing/overdosing)'	Changed.
610-629	3.	**Comment:** In this Annex, the issue of systematic differences between data collection systems is addressed. Instead of developing a harmonised system, now the description of different systems is addressed. But it remains open how data from these different systems are combined in the report. This problem was already repeatedly addressed. **Proposed change:** The collection of the description of the national systems should be the first step before setting a reporting system which claims harmonisation. There should be a clear description how data from these different systems will be handled.	Comment noted. The guidance refers to the collection of harmonised and standardised data – to the extent possible. It is considered that it is not possible to have a single data collection system in place as the local (national) circumstances are different. A description of the system for collection of data was considered important and a questionnaire

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			proposed (Annex 3) for the purpose.
630-780	3.	**Comment:** The role of this annex is not clear. **Proposed change:** Consider deletion.	The role of the annex is highlighted in the first paragraph. It is needed to provide insight into the selection of a representative sample in case data cannot be collected through a census model and need to be collected through a sample survey model.
643-645	3.	**Comment:** To be able to use the sampling frame, there needs to be available a minimum set of data on the units of sampling, such as contact information (name of owner, full address of location of farm, phone number, etc.) and information enabling farm characterization (type, size, geographical location). **Proposed change:** Not possible for Germany (data protection).	Comment noted.
643-645	5.	The guidance says: „To be able to use the sampling frame, there needs to be available a minimum set of data on the units of sampling, such as contact information (name of owner, full address of location of farm, phone number, etc.) **Comment:** For data protection reasons, personal data on farmers cannot be provided to EMA.	Comment noted. The data would have to be available to the authorities conducting the sample survey. No such data would need to be provided to EMA.
781-805	3.	**Comment:** The details in this annex are very vague. **Proposed change:** On the basis of the previous comments and the updated proposal this description of the variables to be included in the ESVAC templates should be improved.	It is considered that the variable description is sufficiently detailed and now harmonised with table 4.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
781- 782	4.	**Comment:** See previous comments. **Proposed change:** Annex 5 –Data/variables on antimicrobial use data to be provided to EMA.	The title has been adapted.
783-785	4.	**Comment:** See previous comments. **Proposed change:** For data management purposes the data on antimicrobial use to be provided to EMA from the MSs have to be standardized. To ensure this a template will be used to provide data to EMA. The variables proposed to be included in the template are shown in Table 9. Suggest to move Table 9 to the end of the chapter on Antimicrobial use data.	The text has been adapted.
797-799	4.	**Comment:** See previous comments. **Proposed change:** For data on antimicrobial use obtained from a sample survey, data on animal population covered by the survey have to be provided by use of a template in order to ensure standardization for data management. To ensure this a template will be used. The variables that will be included in the template are shown in Table 10.	The text is adapted.
800-801	4.	**Comment:** See previous comments. **Proposed change:** Table 1. Data/variables on antimicrobial use data to be provided to EMA by country and year.	The text is adapted.
803-804	4.	**Comment:** See previous comments. **Proposed change:** Table 10. Data/variables on animal population covered for sample surveys, to be provided to EMA by country and year.	The text is adapted.
p.13	4.	**Proposed change:** Suggest to move it to the end of Chapter 2.	The figure has been moved.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Figure 1			
Questionnaire	4.	**Comment:** "*Coverage of farms/production per animal species/category". "Are exclusion criteria or thresholds applied for the farms/animals included in the data collection (e.g. farms with less than x animals, back yard flocks, petting zoos)?*" It should be indicated that this applies for those countries that collect data by sample survey. "*Are products sold exclusively for use in companion animals included?*" This has to be rephrased. NFSA guess it is meant "*VMPs marketed solely for companion animals".* There can also be some use of human medicinal products **Proposed change:** Are VMPs marketed solely for companion animals included. Add line: Are human medicinal products (HMPs) included?	Exclusion criteria or thresholds are also sometimes applied by countries collecting data through a census model, where holdings are excluded when the number of animals is below a certain threshold (this is the case in the data collection in e.g. the Netherlands and Germany). Further clarification regarding VMPs for companion animals and human medicinal products has been included in the guidance.
Annex 2	9.	**Comment:** About the benefits of collecting and reporting antimicrobial, it is not efficient to try to interpret all data at a macro level. It could be more interesting to leave some freedom of investigation at a local level and to keep these additional data outside of any goal of national data aggregation.	Comments noted. The Annex is not intended to preclude any use of the collected data at a local level. A sentence referencing the analysis of data at a local level has been included.
Annex 2	9.	**Comment:** There is a risk of misinterpretation of data per species in front of the great difference between modes and conditions of production through EU. FESASS has also a great concern about communication on these. The guidance should stress the necessity of a prudent use of these data and must recommend an analysis of the local context before any use.	It is acknowledged that communication on any results would have to be carefully undertaken including adequate disclaimers on the interpretation of the results.