

## ANTIMICROBIAL RESISTANCE PROGRAMS IN THE EUROPEAN UNION

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### Abstract:

**INTRODUCTION:** Antimicrobial resistance is one of the topical issues that is part of the “One Health” concept with implications for animal health, human health, and even environmental “health”. At the European Commission (EC) level, legislation has been issued for the monitoring of antimicrobial resistance and these rules are applicable by each Member State (MS). For the proper implementation of the above legislation, audits are carried out in Member States that have developed programs on antimicrobial resistance that go beyond the EC’s requests.

**OBJECTIVES:** The aim of the study was the analysis of existing data reports, legislation and recommendations on antimicrobial resistance through which surveillance and monitoring is carried out in the European Union (EU).

**METHODS:** The audit reports issued between 2015 and 2017 by the Food Veterinary Office (FVO), as well as the articles and studies issued by the EC through the antimicrobial resistance institutes were analysed.

**RESULTS:** The FVO conducted audits to “evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal populations and food” in 12 MS, and audits to “gather information on the prudent use of antimicrobials in animals” in 8 MS. These are countries that have very well implemented the EC’s requests and included the “One Health” perspective in antimicrobial resistance programs. Some Member States have risk management strategies for reducing antimicrobial resistance for more than 20 years. They have carried out research projects on antimicrobial resistance. There is an action plan on antimicrobial resistance at the EC level, but their implementation and understanding up to the level of all actors involved in this issue varies from MS to MS. Antimicrobial resistance in the animal population is a topical issue, notoriety among the actors involved, as well as an interdisciplinary problem with indirect results. The same principle of antimicrobial resistance in animals is applicable to humans and the environment as such, this problem can be embedded in the concept of “One Health”. The overall objective of the MS is to generate knowledge and tools to “combat” antimicrobial resistance in animals, humans and even the environment.

**CONCLUSION:** As a conclusion, in order to improve and optimize antimicrobial resistance programs, a “good practice guide” can be achieved by MS with extensive experience in this area, to be used by MS with a more precarious application and over time to harmonize antimicrobial resistance programs within the EU.

**UDC Classification:** 616.9; **DOI:** <http://dx.doi.org/10.12955/cbup.v6.1281>

**Keywords:** antimicrobial resistance; One Health; good practice guide

### Introduction

Antimicrobial resistance is one of the topical issues that can be integrated into the “One Health” concept with implications for animal health, human health, and even the “health” of the environment (Travis et al., 2014; Queenan et al., 2016). Often, waste produced at the farm level through treatment plants can transfer antibiotic residues to the soil, and from the soil these residues can be transferred to food products of non-animal origin, and thus indirectly, people and other animals get antimicrobial resistance (Marathe et al., 2013; Call et al., 2013; Larsson, 2014).

Antimicrobial resistance is a threat to economic safety, food safety, and even human security. A decrease in antimicrobial resistance in animals with best practice guidelines and the uniform application of measures at least in the Member States (MS) and the application of alternative treatments (without antibiotics) may reduce antimicrobial resistance in people in the future (O’Neill, 2016).

One of the objectives of this article is to understand the steps taken by the European Commission (EC) and MS to reduce antimicrobial resistance and to increase awareness that people themselves are responsible for diminishing antimicrobial resistance, not just the main actors represented by state institutions, European institution and so on. People need to be re-educated in regard to the use of antibiotics, but also in regard to the application of antibiotic treatments (veterinarians, human doctors). Programs developed by the EC for MS and also by each MS are important steps in reducing antimicrobial resistance.

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## Material and Methods

In this paper, the audit reports issued by the FVO were studied, in addition to the annual reports of the European Food Safety Authority (EFSA) and European Centre for Disease Prevention and Control (ECDC) on antimicrobial resistance, and the programs and reports issued by some Member States in order to reduce antimicrobial resistance (DG SANTE, 2016a-f; DG SANTE, 2017a-d; EFSA and ECDC, 2016, 2017).

## Results and Discussion

The most relevant EU legislation on antimicrobial resistance is the Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. MS perform the monitoring of antimicrobial resistance and, in order to uniformly apply this monitoring and to harmonize reporting, the Decision no. 2013/652/EU was issued on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (Decisions 2013/652/EU).

These rules are applicable in each MS, and annually funding is provided by the EC for the proper implementation of these rules. FVO audits carried out in the Member States have two major goals. The first one is to verify and “evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food producing animal populations and food”. The second is to gather information on the prudent use of antimicrobials in animals (EFSA and ECDC, 2011). Audits assessment began in 2015 with Denmark and Germany, and by the end of 2017, 12 MS were already evaluated. The FVO’s experts recommended actions toward the improvement of reducing antimicrobial resistance and the uniform application of standards programs transmitted by the EC.

The EC interest in antimicrobial resistance became known at the end of the 20th century and gave birth to the Directive 2003/99/EC and subsequently the Decision 2013/652/EU.

The FVO mission reports analysis revealed that, for the accession of certain countries to the EU, the Directive 2003/99/EC has been phased in to understand the difference in the application of the principles in the countries who have recently joined. But, the MS that have established the EC basis, also do not have the same implementation nor supervision of antimicrobial resistance, and hence all activities can be improved.

Also, the audit mission’s reports undertaken by the FVO revealed a rather large gap between MS, as is evident from the number of recommendations issued by the FVO experts.

The recommendations issued for each MS vary between 3 and 6 and the total number of recommendations for all 12 MS already audited was 36 (Table 1).

Recom- mendation Code #	Recommendations
1.	To ensure that all <i>Salmonella</i> isolates tested for antimicrobial susceptibility are originating from domestically produced animals, as stipulated in point 2.3.1. of part A of the Annex to Decision 2013/652/EU.
2.	To ensure that the targets for the antimicrobial resistance monitoring plan are in line with point 2.2 of Part A of the Annex to Decision 2013/652/EU and when the number of isolates required cannot be achieved for specific bacterial species and type of sample of animal population or food category.
3.	To ensure that the allocation of the number of samples at the slaughterhouse is proportional to the number of domestic animals slaughter and that the batches are randomly selected.
4.	To ensure that the collection of samples at slaughterhouses is evenly distributed over each month of the year, that the allocation of the number of samples to be collected in each slaughterhouse is proportional to the annual throughput of the slaughterhouse and that batches are randomly selected in line with Article 2(2) and in particular points 2.3 and 2.3.1 of Part A of the Annex to Decision 2013/652/EU.
5.	To ensure that the sampling procedures at retail level ensure that the isolates obtained are representative of the food categories tested, as required by Article 2.2 and point 1 of part A of the Annex to Decision 2013/652/EU.
6.	To ensure that the information included in the report is complete by using all the electronic collection forms provided by the European Food Safety Authority and in particular that the overall description of the implementation of antimicrobial resistance monitoring is provided in line with requirements of Article 5 and of points 2 and 2.1 of Annex B of Decision 2013/652/EU.
7.	To ensure that sampling is performed according to the planned activities in order to ensure that the

	minimum number of isolates tested for antimicrobial susceptibility is achieved for each combination of bacterial species and animal population in line with Article 2(2) and in particular points 2.3. and 2.3.1. of Part A of the Annex to Decision 2013/652/EU.
8.	To ensure that laboratories designated for official antimicrobial resistance monitoring align all steps of the dilution methods used for antimicrobial susceptibility tests in accordance with the methods described by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) and the Clinical and Laboratory Standards Institute (CLSI), in order to comply with the point 3 of Part A of Decision 2013/652/EU as required by Article 4(1)(a) of Decision 2013/652/EU.
9.	To ensure that the information included in the report is complete by using all the electronic collection forms provided by the European Food Safety Authority and in particular that the overall description of the implementation of antimicrobial resistance monitoring.
10.	To put in place mechanisms that ensure that the information included in the report sent to the European Food Safety Authority on each individual sample is complete and accurate in line with requirements of Article 5 and of point 2 of Annex B of Decision 2013/652/EU.
11.	To ensure that laboratories designated for official antimicrobial resistance monitoring align all steps of the dilution methods used for antimicrobial susceptibility tests.
12.	To ensure that the staff collecting samples in the framework of Decision 2013/652/EU are provided with access to the necessary slaughterhouses to ensure that sampling is performed in slaughterhouses processing at least 60% of the broiler domestic population, in order to fulfil the requirements of point 2.3 of Part A of the Annex to Decision 2013/652/EU.
13.	To ensure that sampling at slaughterhouses and retail is representative, as set out by Article 2(1) and points 2.3 and 2.3.1 of Part A of the Annex to Decision 2013/652/EU, namely by allocating samples to the minimum population targets, recovering the minimum required <i>C. jejuni</i> isolates and distributing samples evenly over each month of the year.
14.	To ensure that the information available allows for the exclusion of repeated epidemiological units to comply with point 3 of Part A of the Annex to Decision 2013/652/EU and the samples taken at retail comply with point 2.3.3 of the said Part A.
15.	To ensure that, when the minimum number of <i>Salmonella</i> isolates from different epidemiological units required by point 2.2 of Part A of the Annex to Decision 2013/652/EU to be subject to antimicrobial susceptibility testing are not achieved, all available <i>Salmonella</i> isolates are subject to antimicrobial susceptibility testing, in order to comply with Article 2(2)(a) of the said Decision.
16.	To ensure that the coordination role of the National Reference Laboratory for antimicrobial resistance, the laboratory documented procedures and the storage of the isolates are in line with points 3, 4 and 5 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 of Decision 2013/652/EU and Article 33 of Regulation (EC) No 882/2004.
17.	To ensure that the information included in the overall description of the implementation of antimicrobial resistance monitoring provided to the European Food Safety Authority is complete and accurate, as required by points 2 and 2.1 of Part B of the Annex to Decision 2013/652/EU, in order to comply with Article 5 of the said Decision.
18.	To ensure that, when the minimum number of <i>Salmonella</i> isolates required to be subject to antimicrobial susceptibility testing by point 2.2 of Part A of the Annex to Decision 2013/652/EU are not achieved, all available <i>Salmonella</i> isolates are gathered and subject to antimicrobial susceptibility testing, in order to comply with Article 2(2)(a) of the said Decision.
19.	To ensure that sampling at slaughterhouses is representative, as set out by Article 2(1) and points 2.3 and 2.3.1 of Part A of the Annex to Decision 2013/652/EU, namely by allocating samples at this level on the basis of domestically produced animals and by ensuring that batches are randomly.
20.	To ensure that the samples are preserved and transported in line with documented procedures in place and that they are in line with point 4 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 (1) of the said Decision.
21.	To ensure that adequate documented procedures and quality controls are in place so that test results (for both the minimum inhibitory concentration determination tests and the specific monitoring of ESBL- or AmpC- or carbapenemases-producing <i>E. coli</i> ) are obtained in line with points 3, 4 and 5 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 of the said Decision.
22.	To ensure that the documented procedures in place, and their effective use, for the specific monitoring of ESBL- or AmpC- or carbapenemase-producing <i>E. coli</i> are in line with the European Reference Laboratory protocol and isolates resistant to cefotaxime or ceftazidime or meropenem are tested with a second panel of antimicrobial substances, as requested by point 4.1 and in line with point 4.2 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 of the said Decision.
23.	To ensure that the documented procedures, and their effective use, for the minimum inhibitory concentration determination test, are in line with the relevant standards as requested by point 3 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 of the said Decision.
24.	To ensure that the coordination and cooperation between competent authorities and the gathering of isolates from food business operators allow that the available <i>Salmonella</i> isolates, from the populations specified in point 1 (a) of Part A of the Annex to Decision 2013/652/EU, are gathered and subject to antimicrobial susceptibility testing, in order to achieve the minimum number required by point 2.2 and comply with Article 2(2)(a) of the said Decision.

25.	To ensure that the supervision procedures in place at different competent authority levels guarantee that the design and implementation of the monitoring provide for sample representativeness, as set out by Article 2(1) and points 2.3 and 2.3.1 of Part A of the Annex to Decision 2013/652/EU.
26.	To ensure that sampling at slaughterhouses is representative, as required by Article 2(1) and point 2.3.1 of Part A of the Annex to Decision 2013/652/EU, by evenly distributing samples over each month of the year, by randomly selecting sampling days and by avoiding sampling repeated epidemiological units.
27.	To ensure that sampling at retail is representative, as required by Article 2(1) and point 1 of Part A of the Annex to Decision 2013/652/EU, namely by distributing samples over each month of the year.
28.	To ensure that all methods applied for the official analysis of samples are included in the scope of accreditation of the laboratory, either as an individual test or a group of tests, as required by Article 33.3 in conjunction with Article 12 of Regulation (EC) No 882/2004.
29.	To ensure that the documented procedures in place and their performance (for both the minimum inhibitory concentration determination tests and the specific monitoring of ESBL- or AmpC- or carbapenemases-producing <i>E. coli</i> ) are in line with the relevant standards as requested by point 3 of Part A of the Annex to monitoring of ESBL- or AmpC- or carbapenemases-producing <i>E. coli</i> are in line with the relevant standards as requested by point 3 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 of the said Decision.
30.	To ensure that sampling at slaughterhouses is representative, as set out by Article 2(1) and point 2.3.1 of Part A of the Annex to Decision 2013/652/EU, namely by allocating samples at this level on the basis of domestically produced animals and distributing samples evenly over each month of the year
31.	To ensure that the documented procedures in place, and their effective use (for both the minimum inhibitory concentration determination tests and the specific monitoring of ESBL- or AmpC- or carbapenemase-producing <i>E. coli</i> ) are in line with the relevant standards and with the European Reference Laboratory protocol respectively as requested by points 3 to 5 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 of the said Decision.
32.	To ensure that the information reported to the European Food Safety Authority is accurate, in particular with regard to the sampling and isolation date and the total number of units tested as required in point 2 of Part B of the Annex to Decision 2013/652/EU, in order to comply with Article 5 of the said Decision.
33.	To ensure that sampling at retail is representative, as required by Article 2(1) and point 2.3.3 of Part A of the Annex to Decision 2013/652/EU, namely by covering the minimum population targets and by taking samples without preselecting meat based on their origin.
34.	To avail of adequate documented procedures and to put in place quality controls in order to ensure that tests (the minimum inhibitory concentration determination tests and the specific monitoring of ESBL- or AmpC- or carbapenemases-producing <i>E. coli</i> ) are performed in line with points 3, 4 and 5 of Part A of the Annex to Decision 2013/652/EU in order to comply with Article 4 of the said Decision.
35.	To ensure that the minimum number of isolates derived from turkey caecal samples required by point 2.2 of Part A of the Annex to Decision 2013/652/EU is subject to antimicrobial susceptibility testing.
36.	To ensure that sampling at slaughterhouses is representative, as required by Article 2(1) and point 2.3.1 of Part A of the Annex to Decision 2013/652/EU, in particular by randomly selecting sampling dates and avoiding repeatedly sampling the same epidemiological units.

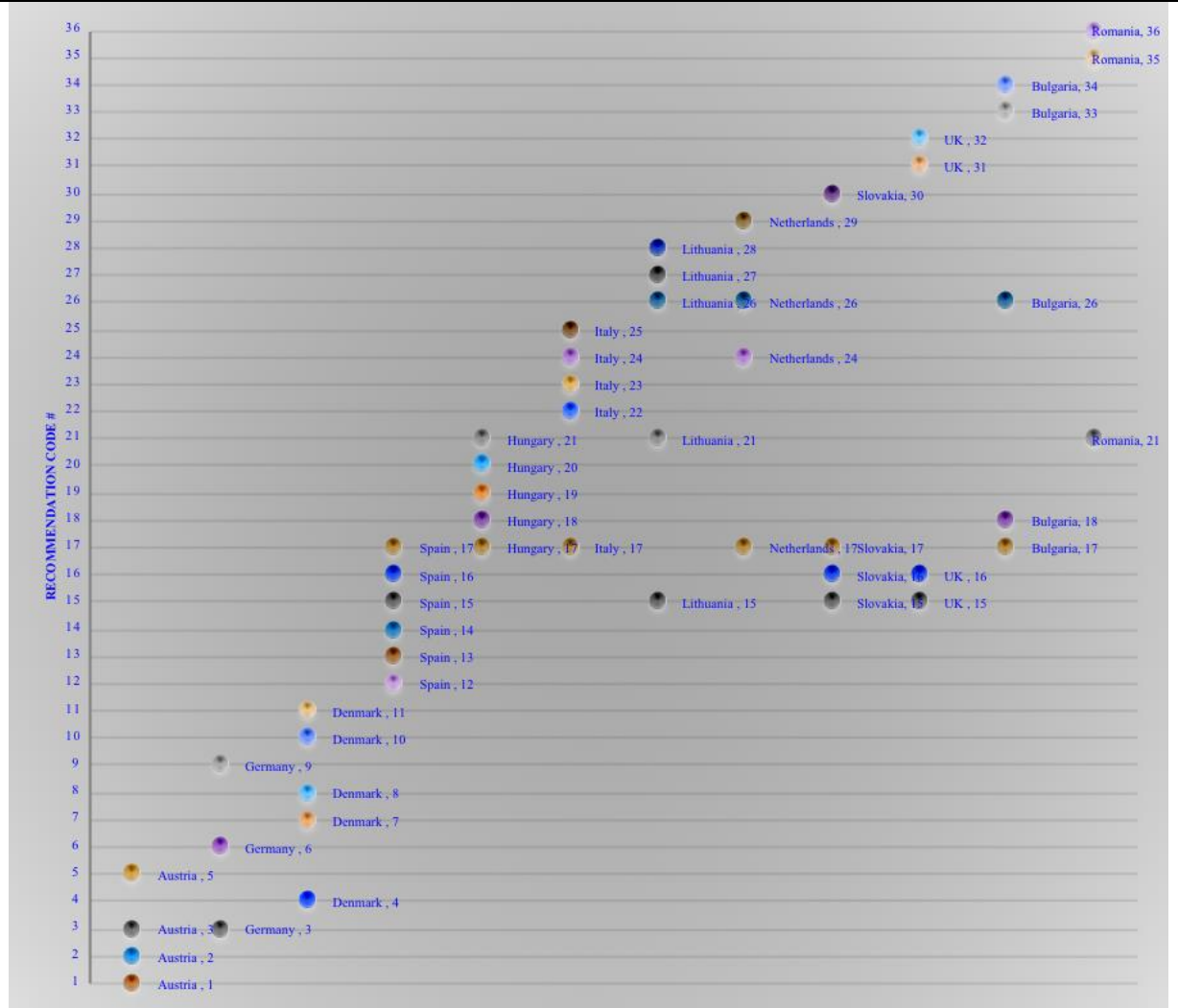
Source: DG SANTE, 2016a-f; DG SANTE, 2017a-d; EFSA and ECDC, 2016, 2017

Usually, each member state received specific recommendations: 77.78% (28/36) received recommendations that were specifically raised for a single member state. The #17 recommendation - “To ensure that the information included in the overall description of the implementation of antimicrobial resistance monitoring provided to the European Food Safety Authority is complete and accurate, as required by points 2 and 2.1 of Part B of the Annex to Decision 2013/652/EU, in order to comply with Article 5 of the said Decision” was the most frequent. That is underlining the doubt on the quality of reported data as being the most frequent challenge. This recommendation was present in the audit reports for six countries: Spain, Hungary, Italy, the Netherlands, Slovakia and Bulgaria (Figure 1).

There are MS that have properly implemented the European Commission's requests and the approach of the antimicrobial resistance programs is a holistic one, in the frame of the “One Health” concept. Some Member States have risk management strategies for reducing antimicrobial resistance for more than 20 years. These countries have carried out research projects on antimicrobial resistance and have developed their own rules on antimicrobial resistance even before the EC called for these activities or when EU legislation was implemented in 2003. As evidenced in the FVO report, Denmark is one of the MS that has developed antimicrobial resistance programs that go beyond the demands of the EC and has conducted concrete action since 1997, being the country that has taken the most steps to reduce antimicrobial resistance and has recorded the expected results. In the One Health approach it is necessary to remove antimicrobials used as growth promoters in animal feed in all Member States, and

even worldwide, to appeal to environmentally friendly treatments, without repercussions on the health of people, and to use antimicrobials only when they are needed (DG SANTE, 2016e).

Figure 1: Recommendations the audited countries by FVO experts. The recommendations issued for each Member State (MS) vary between 3 and 6 and the total number of recommendations for the 12 MS already audited is 36



Source: DG SANTE, 2016a-f; DG SANTE, 2017a-d; EFSA and ECDC, 2016, 2017

At the EC level, there is an action plan on antimicrobial resistance, but its implementation and understanding by all actors involved (each one at their own level) is different for each of them. Sometimes, it could be difficult even for different regions of the same Member State to implement antimicrobial resistance plans, especially as each country has its own culture of animal breeding and its own understanding of the antimicrobial resistance threat. In 2016, the Council of Europe called for a new action plan on antimicrobial resistance according to the “One Health” concept, this plan was developed and published in 2017. Each Member State transposed and adopted its own plan for implementation in line with those requested by the EC and the One Health principles. In 2017, the FVO conducted a joint audit mission with ECDC in Luxembourg, to discuss antimicrobial resistance policies in the light of the new concept; it was concluded that “Limited activities have been undertaken to date to raise awareness on Antimicrobial Resistance (AMR), and a One Health national action plan on AMR is currently in preparation. Although the available data suggest that the use of antimicrobials in animals is relatively low, this is likely to under-estimate the total use, given that antimicrobials supplied to farmers by veterinarians based in neighbouring Member States are not included in this data. Few actions have been undertaken to promote the reduction and more prudent use of antimicrobials in animals and to scrutinize more closely the use of critically important antimicrobials.

Limited AMR surveillance data are available to competent authorities and, in particular, no data is given for companion animals” (Commission Notice, 2015; DG SANTE, 2017d).

Romania annually develops and implements the coordinated control plan for the monitoring of antimicrobial resistance and related technical instructions and the collection of the evidence necessary to comply with Decision 2013/652/EU. Following the FVO mission in 2016, three recommendations were issued to improve the work on reducing antimicrobial resistance and to apply the European Commission’s requests in a uniform manner (Figure 1).

Analysing the audit reports of the FVO on gathering information about the antimicrobial resistance, they emphasise the same critical aspects as the assessment reports on the activities to reduce antimicrobial resistance, namely the differences in MS implementation of the rules and the implementation of action plans for diminishing antimicrobial resistance, such as:

- In Cyprus the report concludes that “Very little has been done to date in the veterinary field to reduce the use of antimicrobials and encourage their prudent use. Whilst some initiatives have started, most actions in this area are prospective and are contingent upon the Ministry of Agriculture’s approval of the draft action plan, which is still being elaborated by the Veterinary Services” (DG SANTE, 2016d).

- In Spain the report concludes that “it is too early to see how effective the AMR action plan will be, there are indications that significant reductions in the use of antimicrobials in Spain can be achieved without adversely affecting productivity and costs. Spain was the highest user of veterinary antimicrobials in 2014 of the countries providing data to the European Surveillance of Veterinary Antimicrobial Consumption project and, according to the Spanish Agency for Medicines and Medical Devices, sales have increased further during 2015. Spain is also one of the highest users of antimicrobials in human medicine” (DG SANTE, 2016c).

- In Finland the report concludes that “the comprehensive and long-standing policies on the availability of antimicrobials, including critically important ones, together with initiatives to raise and maintain the awareness of antimicrobial resistance, have resulted in a relatively low and stable level of sales of antimicrobials and, at the same time, encouraged their prudent use. These factors have been reinforced with actions to enhance the animal health situation and various aspects of the measures put in place in Finland aimed at encouraging the prudent use of antimicrobials in animals and tackling the broader issue of antimicrobial resistance could serve as examples of potential good practice in other Member States” (DG SANTE, 2016b).

- In Romania the report concludes that “measures are supported by regular official controls throughout the distribution and use of veterinary antimicrobial products. These controls will help encourage the prudent use of veterinary antimicrobials. Likewise, the wide range of training and other awareness raising activities carried out have helped familiarise farmers and veterinarians with AMR and general principles for the reduced and prudent use of antimicrobials. However, these have so far had little effect on the prescribing behaviour of veterinarians which is influenced by other factors including price and withdrawal period, especially regarding critically important antimicrobials. The report acknowledges that once the national AMR strategy is fully implemented there is potential for reduced and more prudent use of antimicrobials in animals, especially if certain constraints (notably the cost of diagnostic and susceptibility tests and of medicines) were also addressed. In 2014 the use of veterinary antimicrobials in Romania was below the average reported by the countries providing data to the European Surveillance of Veterinary Antimicrobial Consumption project and a slight decrease in use was seen in 2015. This situation is explained in part by their historically limited availability and their relatively high cost” (DG SANTE, 2016a).

The EFSA has issued technical specifications, reporting manuals and reporting guidelines. On this basis each MS shall submit annually to the EFSA a report on the actions of the previous year, undertaken for supervision/monitoring antimicrobial resistance and the actions to reduce antimicrobial resistance. Based on the reports submitted by MS, the EFSA prepares an annual report, “The European Union Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in the European Union” (UK VARSS, 2017). International institutions have issued good practice guidelines on diminishing antimicrobial resistance, but it is currently necessary to raise awareness on this issue not only to the actors directly involved in antimicrobial resistance (doctors, veterinarians, breeders, researchers) but mainly to the public at large and those who are indirectly

involved (people who simply use antibiotics without need, and so on). In all MS, if samples of pork or beef monitored for antimicrobial resistance are positive, these samples are traced back and investigated for, *Salmonella* spp. or *E. coli*: the positive result is followed by a notification by the Rapid Alert System for Food and Feed (RASFF) to all levels (central, regional and local). The contaminated products are traced back and reserved under restrictions, until the results of the typing are ready and then different measures are applied (general measures: effective cleaning and disinfection of the premises and equipment are carried out and monitoring too). But, regarding antimicrobial resistance, no measures are applied.

## Conclusion

Antimicrobial resistance is a chronic problem being an “invisible killer” for animals, humans and the environment. Antimicrobial resistance in the animal population is a topical issue, notorious among the actors involved, as well as an interdisciplinary problem whose direct results deeply impact everyone’s life, from the farmer to the consumer. The resistance to antimicrobials is an issue of the whole ecosystem, so the same principle of avoiding, limiting, and reducing the antimicrobial resistance must be applied to humans and to the environment for example, through integration of the concept of “One Health”. Antimicrobial resistance today is due to antibiotics used in previous years as growth promoters in animal feed. There even is data showing that for certain antibiotics, there is already antimicrobial resistance before they are placed on the market.

It is necessary to use antibiotics only based on laboratory diagnostic and sensibility tests. Therapy policies must start with the first generation of antimicrobials proven to be effective. The last generation of antibiotic molecules must be used only when the previous molecules failed to cure the antibiotic infection. Through rational use and only in case of need, antimicrobial resistance can be reduced. These principles are valid not only for the animal but also for humans. The final aim of antimicrobials control programs is to no longer use antibiotics as growth promoters and to reserve the use of antimicrobials only for the treatment of identified diseases and only after investigating the sensitivity of the pathogen.

The limited repeatability of the recommendations of the FVO audit report (77% recommendations for a single country) proves that in each state the therapeutic policies, the behaviour and traditions of the main actors in animal husbandry and health, the attitude towards regulations are different, so the weaknesses were different and hence generate specific recommendations for each Member State.

Food producers and retailers need to take steps to improve transparency for consumers regarding the use of antibiotics and to enable better informed decision-making by customers. The overall objective of the Member States is to generate knowledge and tools through which they will “fight” antimicrobial resistance in humans, animals and even the environment.

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