ROADMAP

Rethinking of antimicrobial decision-systems in the management of animal production

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Methodological choices to map the technical-economic and regulation frameworks and identify the socio-technical lock-ins towards a reduced AMU

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About the ROADMAP research project

The overall aim of ROADMAP is to **foster transitions towards prudent use of antimicrobials (AMs) in animal production in different contexts to manage antimicrobial resistance (AMR). Prudent antimicrobial use (AMU) will be achieved by enhancing antimicrobial decision-systems along the food and drug supply chains.** ROADMAP will focus on supporting animal health and welfare through prevention and health promotion actions.

AMR is recognized as a significant threat to global public health and food security. Overuse and improper use of AMs in many parts of the world contribute to the emergence and spread of AMR. Although human and animal health require AMs, it has been estimated that two thirds of the future AMU growth worldwide will be in animal production. Improving the management of AMU in farm animals is therefore a critical component of dealing with AMR and optimizing production in the livestock sector. Nevertheless, the variety of contexts of AMU in the livestock sector is a major challenge to managing AMR. **There is no "one-size-fits-all" solution to improve AMU and strategies must be contextually developed** (for instance, strategies used in the Danish pig industry are difficult to adapt and adopt in the French free-range poultry farming). Successful solutions must be combined and tailored to the production systems and the social and economic context in which they operate.

ROADMAP will meet three general objectives, in line with the EU AMR Action plan: i) **Rethink AM decision-systems and animal health management**; ii) **Develop options for encouraging prudent AMU in animal production**; iii) **Engage all actors in the food and drug supply chains in fostering a more prudent use of AMs.**

Project consortium

Part. N°	Participant organisation name (acronym)	Country
1	Institut National de Recherche pour l'Agriculture, l'Alimentation et l'Environnement (INRAE) **	France
2	Association de coordination technique agricole (ACTA) ***	France
3	Centre de coopération internationale en recherche agronomique pour le développement (CIRAD) **	France
4	University of Liverpool (ULIV) *	United Kingdom
5	Cardiff University (CU) *	United Kingdom
6	James Hutton Institute (HUT) **	United Kingdom
7	Alma Mater Studiorum - Università di Bologna (UNIBO) *	Italy
8	Aarhus Universitet (AU) *	Denmark
9	Eigen Vermogen van het Instituut voor Landbouw en Visserijonderzoek (EV-ILVO) **	Belgium
10	Research Institute of Organic Agriculture (FiBL) **	Switzerland
11	Stichting Wageningen Research (WR) *	Netherlands
12	Swedish University of Agricultural Sciences (SLU) *	Sweden
13	Southern Agriculture and Horticulture Organization (ZLTO) ***	Netherlands
14	European Forum of Farm Animal Breeders (EFFAB) ****	Netherlands
15	Fundacion Empresa Universidad Gallega (FEUGA) ****	Spain
16	Dierengezondheidszorg Vlaanderen (DGZ) ***	Belgium
17	INRAE Transfert (IT) ****	France

** Universities/veterinary schools*
*** Research institutes specialized in both fundamental and applied agricultural and veterinary sciences*
**** Public and private advisory services Organisations*
***** Knowledge transfer and Innovation organisations*

Acronyms

ACD	Animal course dose
ADD	Animal daily dose
AIS	Agricultural innovation systems
AM	Antimicrobial
AMR	Antimicrobial resistance
AMU	Antimicrobial use
CS	Case study
DCD	Defined course dose (for humans)
DDD	Defined daily dose (for humans)
DCDvet	Defined course dose for animals (elaborated by ESVAC)
DDDvet	Defined daily dose for animals (elaborated by ESVAC)
EEA	European Economic Area
EMA	European Medicines Agency
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
FSC	Food-supply chain
FAO	Food and Agriculture Organization
LPS	Livestock production systems
MAH	Marketing authorization holder
OIE	World Organisation for Animal Health – Office International des Epizoozies
PCU	Animal population corrected unit
T	Task
UK	United Kingdom
UN	United Nations
VC	Value chain
VMP	Veterinary medicinal product
WHO	World Health Organization
WP	Work-Package

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1 Summary

The ROADMAP Project aims at supporting transition towards a more prudent use of antimicrobials (AMs) in livestock farming. The ROADMAP project applies a systems thinking approach based on three main conceptual frameworks: the agricultural innovation systems (AIS), the value chain/food-supply chain (VC/FSC), and the socio-technical transition pathways. The structure of the Project is designed around 3 main Pillars. The Pillar 1 provides a systemic diagnosis of how the AM decision-systems are structured and how they function with regard to animal health management and veterinary AM use (AMU). The Pillar 2 co-designs innovative and effective strategies to foster a more prudent AMU. The Pillar 3 evaluates the proposed strategies and identify the most efficient transition pathways. Pillars 4 and 5 are concerned with the Project's communication, results' dissemination, and management.

The Work-Package 1 (WP1) is part of the Pillar 1 and aims to understand how the AM decision-systems drive AM use. WP1 builds on an integration of the AIS and the VC/FSC frameworks. With respect to the VC/FSC, the AIS focuses also on non-business actors (e.g. public extension, civil society, public agencies, research and education, and NGOs) and structural characteristics (e.g. networks, capacities, informal institutions, culture and social norms). On the other side, the VC/FSC highlights on the flows of materials and value creation throughout the FSC, the business models and market institutions, and the power relationships between FSC players. WP1 identifies the most AM consuming livestock production systems (LPSs) by assessing their respective levels of AMU (Task T1.2). In addition, the investigation focuses on the main determinants of animal health management and AMU, i.e. the regulatory and institutional framework and its evolutionary trends, including the development of private standards (Task T1.3), the livestock products' supply chain and the animal health system (Task T1.4). This complex is analysed as a system of institutional, technical, economic, and social relationships and feedbacks among the many actors and interest groups who condition AMU choices. The final WP1 task (Task T1.5) sums up the results of WP1 and WP2: i.e. the two WPs involved in the Pillar 1, where WP2 focuses on the farm level and operators' individual behaviours.

T1.2 is developed taking information from national and international statistics of AMU and from the project case studies (CSs). Information from case studies on the type of data available and on the characterization of LPSs are collected through two questionnaires. Then, information on the evolution of AMU in CS farms and other animal health and economic indicators is collected. The analysis of data is aimed at identifying the prevailing AMU trends and their intensity at the country and LPS levels.

T1.3 analyses national strategies supporting a more prudent veterinary AMU and AMR control in farms and the FSC. Through a standard report outline the project partners collect information related to the different type of measures forming the policy mix deployed in each country, main objectives are: to evaluate how the national strategies fit with the guidelines suggested by European and global institutions, and the level of implementation of the new European legislation on veterinary medicines and medicated feed attained by the different countries. A final objective is a qualitative assessment of the effectiveness of the adopted measures based several parameters, such as: the reduction of AMU and AMR resulting in the specific monitoring data, the relevance of the adopted measures resulting from comparison between countries, and capacity of implementation.

T1.4 develops a structural-functional analysis of the antimicrobial decision-systems by proceeding in three steps: a descriptive stakeholder mapping, identifying actors, roles and interactions through key informant interviews; a further structural analysis, identifying infrastructures, soft institutions, capabilities, and market structures by stakeholder interviews, document analysis and secondary data anal-

ysis, and linking institutions to actors and interactions; a functional analysis on how structures determine/affect the decision-systems, based on stakeholder interviews, document analysis, participatory observation, and focus groups.

T1.5 merges the results of the two WPs involved in Pillar 1, in order to hierarchize the socio-technical lock-ins towards a reduced AMU identified at both the micro (farm) and macro (FSC and animal health system) levels and indicate priorities for the initiatives of Pillars 2 and 3. The task will be developed after the conclusion of WP1 and WP2 research activities in a later stage of the ROADMAP Project.

2 Introduction and background

2.1 ROADMAP analytical frameworks and project structure

The ROADMAP project aims at supporting transition towards a more prudent use of antimicrobials (AMs) in livestock farming by re-thinking the AM decision-systems in the management of animal production and providing strategies to improve antimicrobial use (AMU). The project intends to give a relevant contribution to the research on this topic, which is mostly technical or interdisciplinary-qualitative [1] and suffers several limitations. Technical studies investigate alternatives to AM for animal production and good practices that reduce the animal health risks driving to AMU, but often do not consider the behavioural aspects, the lack of incentives, and the sociotechnical lock-ins [2–4] hindering possible changes. On the other side, the studies dedicated to farmers' behaviours and attitudes towards AMU and alternative strategies tend to focus on the individual drivers of farmer decisions, by neglecting the relations with the other actors of the animal health system and the food-supply chain, and the wider social, cultural, institutional, and economic context. Such an approach conceptualises AM overuse in livestock farms and related insurgence of AM resistance (AMR) as problems of individual farmer behaviour, while the relevance of systemic conditions and drivers on the decisions and strategies for a more prudent AMU is scarcely considered: this restriction of the research scope to individual attitudes and feelings implies shortcomings that have been highlighted also in other fields of sustainability research [5,6].

To overcome these limitations, the ROADMAP project applies a system thinking approach based on three main conceptual frameworks: the agricultural innovation systems approach, the value chain/food-supply chain approach, and the socio-technical transition pathways approach. The agricultural innovation systems (AIS) originated as an approach to understand the development and spread of innovations in agriculture through the acknowledgement that results from an interactive and co-evolutionary process engaging a wide network of actors (Figure 1).

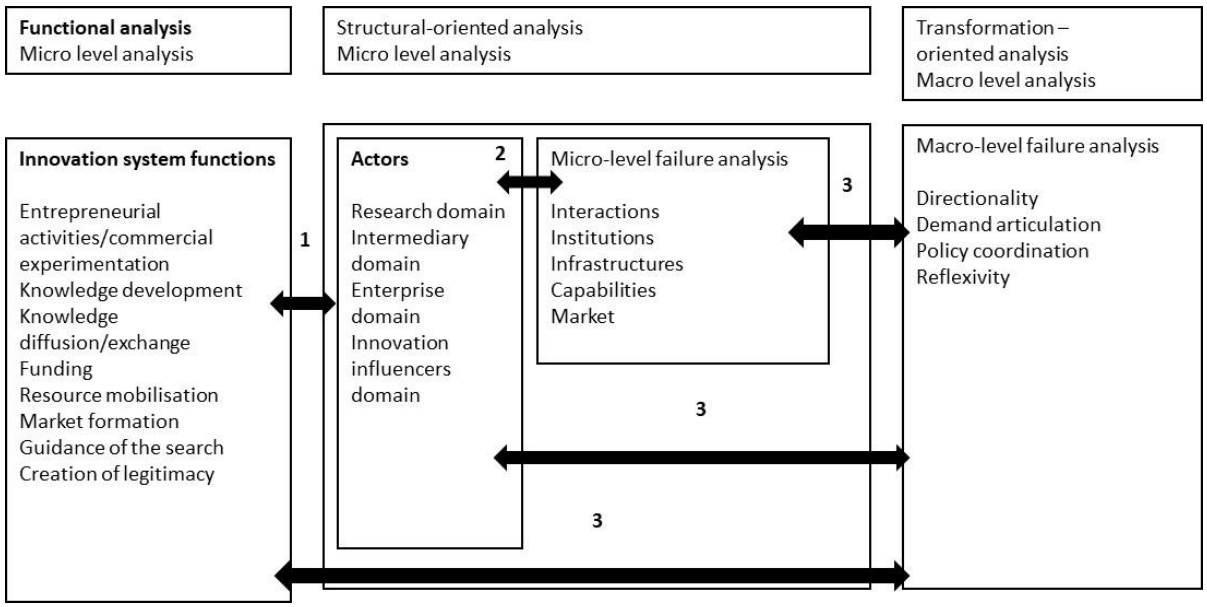

Figure 1 – The AIS framework (from Lamprinopoulou et al., 2014) [7]

The AIS framework takes into account that speed and direction of innovation processes are not only affected by the institutional and policy environment, but also by the divergence in goals of the different actors [7,8]. The AIS framework has been already used for holistic assessments and comparisons of national and sectoral agricultural innovation processes [9,10], or to identify strategies to create a more conducive context for agricultural innovation networks and a more durable embedding for agricultural projects [11]. The ROADMAP Project mainly builds on the conceptual AIS construction of Lamprinopoulou et al. (2014) [7], which combines several related frameworks into an integrated one.

This framework was applied to the systemic analysis of the animal health sector by Gimeno et al. (2018) [12] (Figure 2)

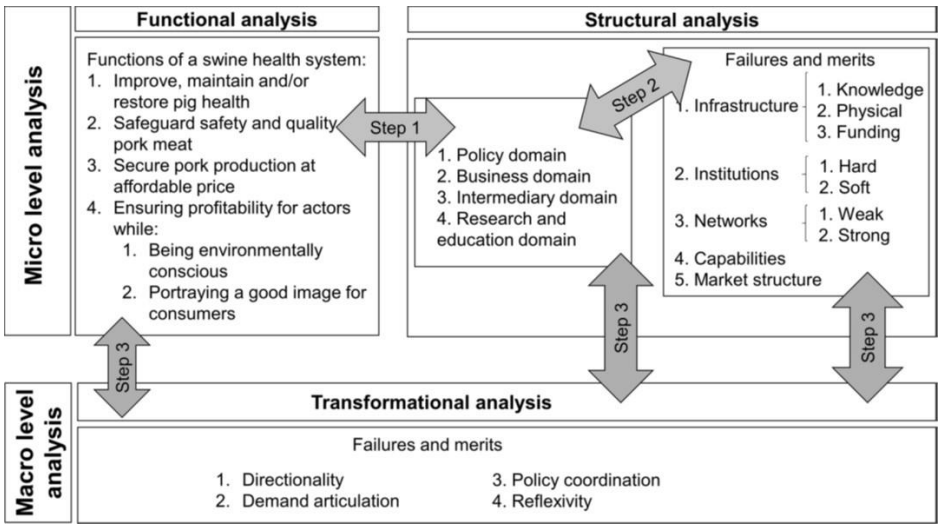

Figure 2 - Analytical systemic framework for investigating the animal health system (from Gimeno et al., 2018) [12]

The value chain/food-supply chain (VC/FSC) framework [13–27] allows to rescale the analysis from the farm level to the systemic drivers and lock-ins, by conceptualising how practices, knowledge and motivations related to animal health management depend on decision-systems involving a wider socio-technical-economic and institutional context. The FSC is generally represented as a four-stage process, where the upstream industries provides inputs to the farming activities for the production of agricultural commodities that are delivered downstream to be processed within the food industry complex and then distributed for final consumption (Figure 3).

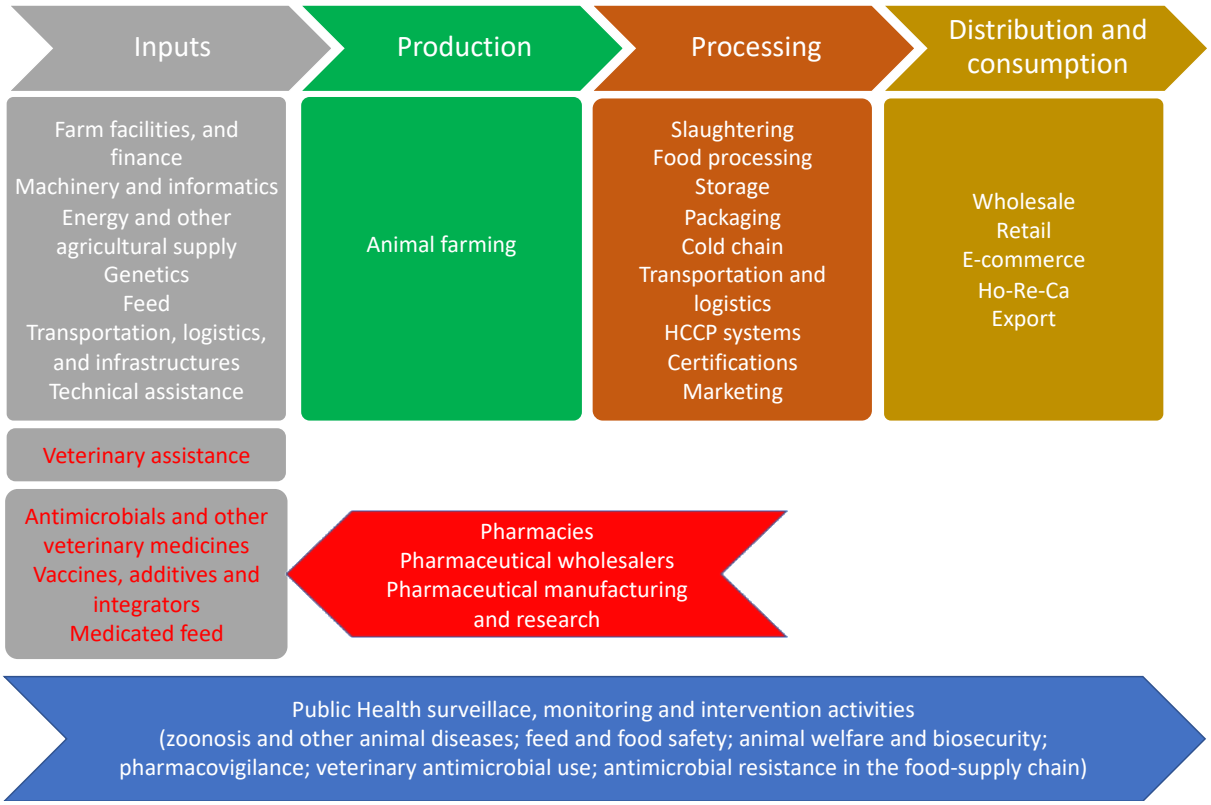

Figure 3 – Representation of the food-supply chain for animal products and its interconnections with the pharmaceutical industry (red arrow) and the public health system (blue arrow)

Moreover, to understand the drivers conditioning the adoption of solutions moderating the AMU in animal farms, the basic FSC scheme needs to integrate the interrelations with the pharmaceutical industry and the activities of the public health sector addressed to animal health and food safety as shown in Figure 3. Beyond consumer preferences and marketing policies of retailers and the food industry, the analysis can thus incorporate the business strategies of the pharmaceutical industry, the interests of the private veterinary assistance and the action of the Public Health services implementing governmental political orientations.

With many promising applications into the agricultural sector [28–33], the multi-level socio-technical transition pathways framework [34,35] operate interdisciplinary studies on the social, economic and technical dynamics of innovation and how novel practices can become compatible with the existing socio-technical regime driving a change. This approach has developed a multi-level model explaining how three types of interactions can create a transition to new practices and knowledge (see Figure 4).

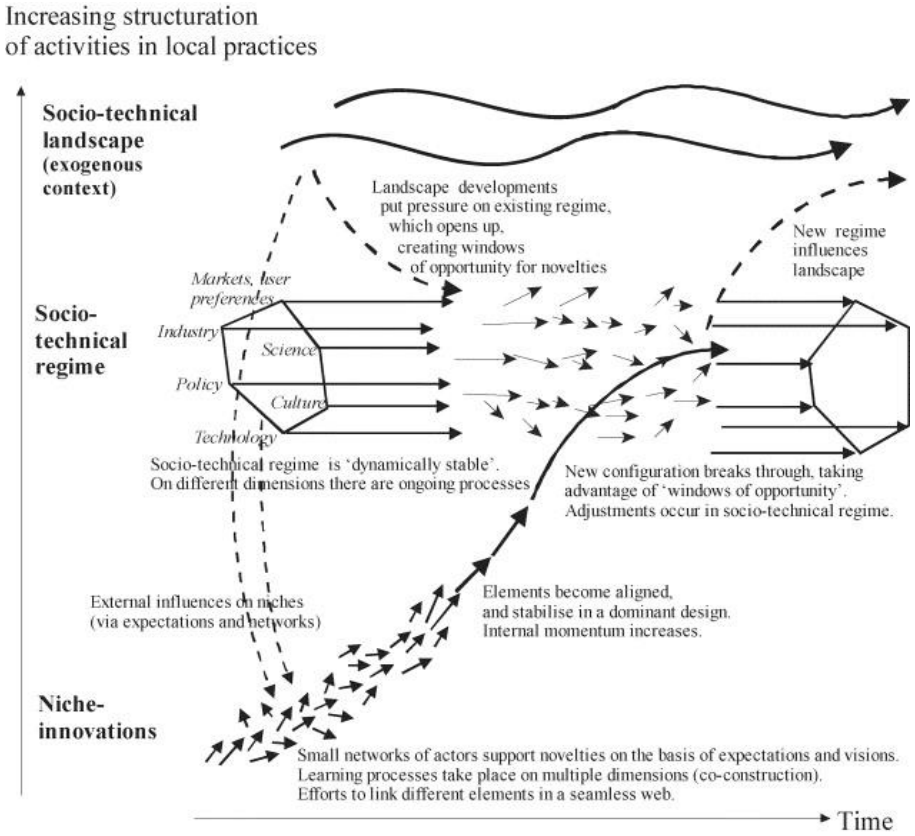

Figure 4 - The multi-level socio-technical transition pathways approach (from Geels and Schot, 2007)[35]

Referring to veterinary AMU, the socio-technical regime takes shape from the prevailing livestock production systems driving farmers' decisions towards conventional AMU practices. The niches-innovations consist in the socio-technical niches creating new solutions supporting a more prudent AMU (e.g., "antibiotic-free" labels). The landscape is given by the social and political context putting pressure on the food industry to reduce AMU: e.g., through stricter standards that remove lock-ins to change in AMU practices.

Combining these three key conceptual frameworks, the structure of the ROADMAP Project is designed around 3 main Pillars (Figure 5 on the next page). The Pillar 1 provides a systemic diagnosis of how the AM decision-systems are structured and how they function with regard to animal health management and AMU. The focus is on the overall management of animal health, because any of its elements can have effects on how much AMU is needed to safeguard animal productivity, health and welfare. This Pillar is mainly built on the AIS and the value chain/food-supply chain frameworks. The Pillar 2 co-designs innovative and effective strategies (technical, economic, social and institutional) to foster a more prudent AMU, by applying them – when feasible – in field settings. Pillar 2 mainly builds on the transition pathways framework, using insights from Pillar 1. The Pillar 3 evaluates the proposed strategies and identify the most efficient transition pathways, building on the two previous Pillars. Pillars 4 and 5 are concerned with the Project's communication, results' dissemination, and management.

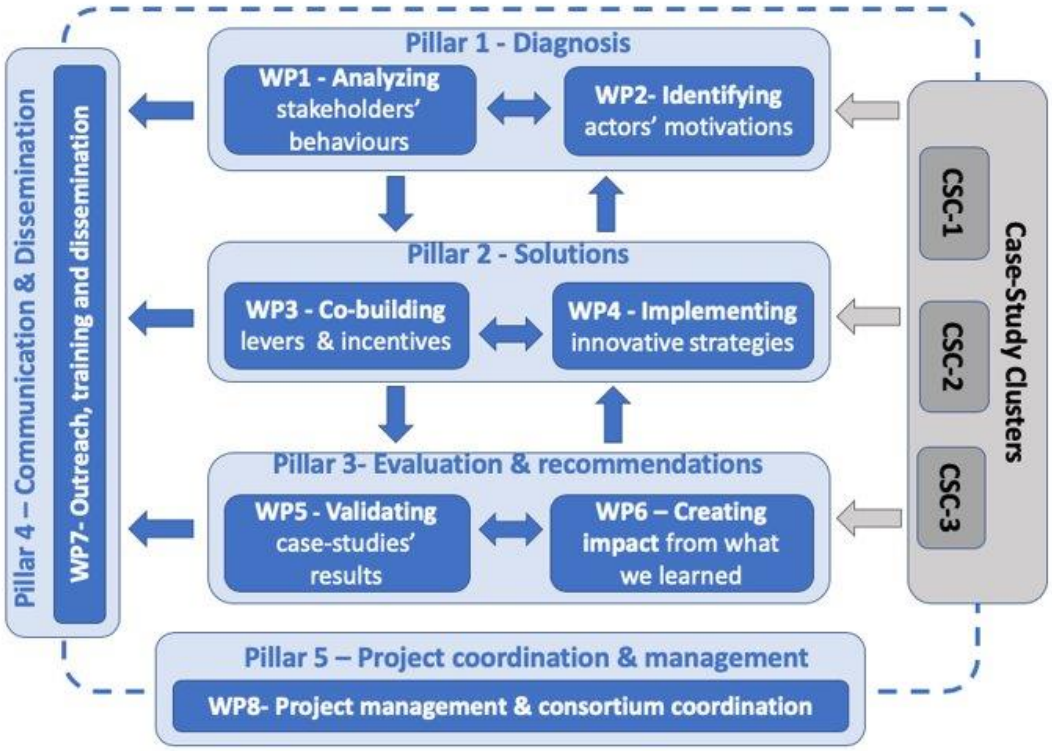

Figure 5 – Overall structure of the ROADMAP Project

2.2 Work-Package 1: objectives, overall approach and relationship to other work packages

The ROADMAP Work-Package 1 (WP1) is part of the Diagnosis Pillar and aims to understand how the AM decision-systems drive AMU. WP1 builds on an integration of the AIS and the VC/FSC frameworks. Both are centred around the system's actors, their influence and interests, the type and nature of interactions between them and the institutions governing their behaviour and their interactions with other actors. The AIS adds to the VC/FSC approach a focus on non-business actors, such as public extension, civil society, public agencies, research and education, and NGOs, and the emphasis on structural characteristics, such as networks, capacities, informal institutions, culture and social norms. On the other side, the VC/FSC adds to the AIS approach the highlights on the flows of materials and value creation throughout the FSC, the business models and market institutions, and the power relationships between the supply chain players.

The WP1 specific objectives are:

- identify the main AM consuming livestock industries and production systems at the European level and assess the respective levels of AMU;
- map and analyse the AM decision-system, i.e. the whole socio-economic, technical, organisational and institutional context determining animal health management and AMU: the upstream and downstream industries of the animal products' supply chain, the veterinary drug market and animal health services, and the regulatory framework, and identify the current evolutionary trends affecting this complex in its different parts;

- identify the main drivers of AMU and the technical, economic, social, and institutional lock-ins that prevent the transition towards an increasingly prudent AMU in livestock farming.

Referring to a geographical scope covering Europe and some selected non-European countries, the research identifies the most AM consuming livestock production systems by assessing their respective levels of AMU (Task 1.2). In addition, the investigation focuses on the main determinants of animal health management and AMU, i.e.: the regulatory and institutional framework and its evolutionary trends, including the development of private standards (Task 1.3), the livestock products' supply chain and the animal health system (Task 1.4). By applying the conceptual frameworks described in §2.1, this complex is analysed as a system of institutional, technical, economic, and social relationships and feed-backs among the many actors and interest groups who condition AMU choices.

The scientific literature and the project case studies are the main sources of information and data. All the project case studies feed inputs in WP1 and the implementation of the described research tasks (T1.2, T1.3, and T1.4) are preceded by a methodological task (T1.1) that identifies the type of data available, the data collection strategies, the elaboration techniques, and the methods to combine the different data and information sources. In general, the implementation of the research tasks includes document analysis, expert interviews, focus groups, and dataset analysis. The final WP1 task (T1.5) sums up the results of WP1 and WP2: i.e. the two WPs involved in the Pillar 1 (Diagnosis). Table 1 shows a breakdown of the WP1 tasks.

Table 1 - WP1 Task breakdown

Tasks	*Details*
Task T1.1 Development of the methodological framework	T1.1 sets up the theoretical and methodological approaches required to implement WP1's tasks.
Task T1.2 Assessment of AMU in the different livestock production systems	T1.2 assesses the levels of AMU in the different livestock production systems (LPS) of Europe and selected non-European countries. The LPS are identified on the basis of species, type of products (including conventional and labelled), and farms' relevant structural characteristics. The task covers pig, poultry and cattle production (milk and beef). The levels of AMU in the different LPS are assessed using data and information available from the literature and existing statistics and from the project's case studies, also through surveys and key respondent interviews.
Task T1.3 Evolutionary analysis of the regulatory and institutional context	T1.3 maps the existing AM regulatory framework in Europe and in selected non-European countries and its current evolution, including the development of private standards. T1.3 examines: (1) the orientations and the global policy strategies on AMU indicated by the international organizations; (2) the relevant national regulations and policies outside the European Union (EU); (3) the EU and Member States legislation and policies; (4) the development of private standards. The analysis includes qualitative evaluations on impacts and effectiveness of the different policy approaches and type of

Tasks	*Details*
	measures. The main sources of information and data are the available in the scientific literature and the project's case studies.
Task T1.4 Systemic analysis of stakeholders' behaviours in the animal products supply chain and the animal health system	T1.4 investigates the animal health system including all the actors influencing animal health management and the AMU in livestock farming, along with the structures and institutions guiding their behaviour. The organization of the downstream and upstream industries of the animal products' supply chains are examined to understand how it affects veterinary AMU and the adaptive strategies of the stakeholders confronted with the evolution of consumers' attitudes and regulations on the issue. A mapping of the relevant actors, roles and relationships of the animal health system is performed. Practices, perceptions, motivations and economic choices of operators analysed. T1.4 develop systemic analyses and models of the stakeholders' behaviours in the current changing AMU framework. The final targets are the identification of main AMU drivers and the economic and socio-technical lock-ins hindering a technological advance towards a more prudent AMU and the creation of a basis for the evaluation (Pillar 3) of possible actions and measures proposed in Pillar 2.
Task T1.5 Integrated WP1-WP2 systemic identification of socio-technical lock-ins and priorities for actions	T1.5 merges the results of the two WPs (i.e. WP1 and WP2) involved in the Pillar 1 (Diagnosis) with the aim of categorising and creating a hierarchy of the socio-technical lock-ins towards a reduced AMU identified and indicate priorities for the initiatives to be designed and evaluated within the Pillars 2 and 3.

While WP1 performs a macro-oriented description and analysis of the antimicrobial decision-system, focusing on all actors, institution and other structural characteristics of the system (T1.2 – T1.4), WP2 results from a more micro-oriented approach, hereby focusing on the motives, attitudes, practices, knowledge and other aspects of the main decision-makers, i.e. the farmers and the veterinarian. The integrate findings of WP1 and WP2 feed into the Pillar 2 (Solutions) and the Pillar 3 (Evaluation and recommendation).

3 Assessment of antimicrobial use in the different livestock production systems (Task 1.2)

3.1 Background, objectives and general strategy of the Task

3.1.1 The detection of AMU in animal production;

In the context of WP1 and the ROADMAP project, the general objective of T1.2 is to assess the level of AMU in animal production systems and the related prevailing trends. The analysis focuses on the European Union (EU) and non-EU countries involved in the ROADMAP project, on other countries relevant for AM consumption and their experiences in the implementation of policies for a more prudent AMU.

The assessment of veterinary AMU for public health monitoring related to the surveillance of AMR in farms and the food supply chain implies many relevant issues in terms of usable information sources, metrics and calculation methods, and standardization and comparability of estimates from different national statistics [36–42]. Currently, despite the tripartite collaboration of three international agencies - the World Organisation for Animal Health (OIE), the World Health Organization (WHO), and the Food and Agriculture Organization (FAO) - publishes each year a global AMU estimates [43], there is not a standard method agreed among national agencies operating AMU assessments at country level: not even within the EU. In addition, also in the private sector many different types of metrics for assessing AMU have been developed; even in a single country, each livestock sector has often its own standards for AMU measurement and this may change at the level of the single industrial group.

Partially, standardized statistics on veterinary AMU for food-producing animals at the European level are however provided by the European Medicines Agency (EMA) through its European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project started in 2010. Since 2011, the ESVAC has been publishing a yearly report that presently surveys 31 countries of the European Economic Area (EEA) and the United Kingdom (UK): i.e. all the current European Union's (EU) Member States, plus Iceland, Norway, and Switzerland. The last report available was published in 2019 and shows the 2017 data [44].

ESVAC statistics report the total AM sales (in weight of active substance) for the various AM classes and the AM sales per animal population corrected units (PCUs) in each country. The survey includes AM agents for intestinal, intrauterine, intramammary, and systemic uses and AM agents belonging to antiparasitic products in the pharmaceutical forms for both treatments: group (premixes, oral powders and solutions) and individual (injectables, intrauterine, and intramammary preparations, boluses and oral pastes).

PCU calculations are based on EU and national statistics about the number of live, slaughtered, and traded livestock of the different species (cattle, sheep, pigs, poultry, horses, and other minor bred animals) in the examined countries, multiplied by respective supposed weight at treatment; for aquaculture only the weight of slaughtered fish is considered. Such a methodology allows comparisons between countries and along time in terms of milligrams of AM active principles sold per PCU (i.e. mgs per kg of food-producing animals' biomass), but indicators of AM use for the different livestock species are missing.

Data provision from Member States to the EMA-ESVAC is currently organized on a voluntary basis and on the rules set at the country level concerning the reporting of veterinary medicinal products (VMPs) sold by marketing authorization holders (MAHs). The new European regulation on VMPs (Reg. No

2019/6) [45] has established (art. 57-59) a compulsory framework for AM sales and use reporting. In particular, the EU Member States will be committed to collect and send to the EMA the data on the volumes of the different AM types sold and the use made per animal species. The new regulation, also relevant for the EEA countries, will be in force in January 2022, while the new reporting obligations apply from January 2024 for the food-producing animal species and categories already monitored for antimicrobial resistance (i.e. laying hens, broilers, fattening turkeys, fattening pigs, and cattle slaughtered under 12-month age) [46], from January 2027 for all the food-producing animal species, and from January 2030 for all bred or kept animals.

The evolution of the EU legal framework is oriented to fill the current knowledge gaps regarding quantification of AMU for the different animal species and categories. On this prospective, during summer 2018, within the ESVAC framework, the EMA launched a project for the stratification of AM sales data by animal species to be implemented by Member States in parallel with the annual ESVAC survey on AM sales. The stratification is based on the direct attribution of sales for the AM VMPs authorized to be administered to a single animal species. The sales of products authorized for multiple species will be attributed to the related species according to the percentage distribution of the total sales. In principle, this information should be provided by the MAHs to the national authorities. Animal species indicated as "mandatory" for the stratification are cattle, pigs, and poultry; other species to be considered for this exercise are sheep and goats, fish, horses, rabbits, cats and dogs, and "others or unknown". Additional information is demanded for chickens, turkeys, and any other species for which AMs were used. The first stratification concerns 2017 AM sales, but this project is only provisional, in view of the setting up of a collection system of detailed data on AM use per each animal category.

Such future collection system of detailed data has been somewhat anticipated by the ESVAC with the finalization, in February 2018, of a "Guidance on collection and provision of national data on AM use by animal species/categories"[47] that defines the data which could be provided in the upcoming years to the EMA by the EU Member States and the other EEA countries involved. The document indicates procedures for quantification of AM use in the same animal species and categories already monitored for AM resistance (Commission Implementing Decision No 2013/652/EU) [46] and also mentioned by the new VMP regulation No 2019/6 as the first that will be under mandatory reporting of AM use in January 2024. In addition, the guidance covers data collection for dairy and beef cattle (including cows, heifers, bullocks and bulls).

Two alternative schemes are proposed for data collection at the national level: a 'census' model, i.e. a continuous automated data collection system almost covering the whole animal production for the analysed animal species/category; and a 'sample survey' model, where data are collected from a highly representative randomly-selected sample of farms or the animal production for the analysed animal species/category. For data reporting, beyond the mg/PCU indicator, the guidance prescribes the introduction of 'defined daily doses' and 'defined course doses' for animals (DDDvet and DCDvet respectively) adjusted by species PCU in kg of animal biomass.

DDDvet and DCDvet are the specific standard indicators elaborated by the ESVAC for reporting the therapeutic use of AM active principles in animal populations [48,49]. They are inspired by the concepts of 'animal daily dose' (ADD) and 'animal course dose' (ACD) introduced in Denmark by Jansen et Al. [36] on the basis of the corresponding indicators already existing for humans [50]. DDDvet and DCDvet are generally based on the dosing information from the Summary Product Characteristics (SPC) of veterinary AMs from the nine EU Member States (i.e. the Czech Republic, Denmark, Finland, France, Germany, Netherlands, Spain, Sweden, and the UK) directly collaborating to the initiative. The ESVAC suggests the use of the acronyms DDDvet and DCDvet only for the European monitoring system, to

avoid confusion with similar indicators developed at country level, also by EU Member States, and by other institutions.

Beyond the methodologies and the guidelines produced, the ESVAC has not yet published data on veterinary AMU per animal species. At the EU Member-State level, the national institutions that manage the monitoring of the AMU apply data collection and analysis methodologies that are rather heterogeneous. For example, some of the countries participating in the ROADMAP project, such as Belgium, Denmark, and the Netherlands, have developed sophisticated methods, based on the national electronic prescription and delivery systems for veterinary medicines and the national livestock databases. In these countries, the national reporting of AMU is integrated into monitoring systems detecting AMU at the level of the single farms and produces data related to the different livestock species and categories [51–54]. The reports also show AMU data in terms of daily doses and course doses, as well as specific indicators adopted at the country level taking into account the animal bio-masse exposed to possibility AM treatments and the time of exposition. However, although similar, the data issued from these countries are not directly comparable, since each country has elaborated its own indicators based on the specific organization of the data collection and the veterinary AMU monitoring systems.

In other countries, like France and the UK, the estimations of national veterinary AMU rely more on the declarations of AM sales made by the MAHs [51,55–57]. In France, for example, the annual report of the competent national agency (ANSES) is based on the MAHs' declarations of AM sales by active principle and related estimated use by the different livestock species. The assessment of the livestock populations and the related amount of animal bio-masse potentially treatable is based on the national agricultural statistics. ANSES estimates ADDs and ACDs referred to the kg of live-weight for the different species (ADDkg and ACDkg), as well as a specific indicator of animal level of exposure to antimicrobials (ALEA) corresponding to the ratio between the number of ACDkg sold and the total estimated animal bio-masse weight for a given livestock species [55]. The UK issues data on national AM sales from MAH declarations based on the ESVAC methodology. Contrarily to France, such data do not indicate the use by livestock species. In parallel, the UK annual report publishes data on AMU by species derived from various sources, often private and provided on a voluntary basis, referring to AM prescriptions, purchase, and administration [56]. Italy issued its first and only, so far, national report on veterinary AM sales in 2019 showing 2016 data already published by ESVAC without any additional information related to use by the different livestock species [57]. However, this country has launched the project ClassyFarm aimed at monitoring many aspects of animal health and welfare in livestock farms including AM consumption. Participation to the project is still voluntary for farmers and veterinarians, AMU data sources are treatment registries, invoices, prescriptions and companies' databases. ClassyFarm does not issue public national reports yet, but its integration within the national electronic prescription system has been planned [51,58].

3.1.2 Specific objectives of the Task

Based on the considerations expressed in §3.1.1, the specific objectives of T1.2 are the following:

- T1.2 aims to assess the levels of AMU in the different livestock production systems (LPSs) of Europe and selected non-European countries;
- the LPSs will be identified on the basis of species, type of products (including conventional and labelled products), and relevant structural features of livestock farms;
- the task will cover pig, poultry and cattle production (milk and beef);

- the levels of AMU in the different LPS will be assessed using data and information available from the literature and existing statistics and from the project case studies, also through surveys and key respondent interviews.

3.1.3 Work organization in sub-tasks

To fulfil the T1.2 objectives, the task work has been organised in 5 sub-tasks:

- T1.2.1 Literature review and collection of existing statistics and estimations at global, European, and country levels;
- T1.2.2 Characterization of case studies' livestock production systems and identification of data available;
- T1.2.3 Collection and analysis of AM use data in case studies' farms;
- T1.2.4 Report writing, deliverable finalization;
- T1.2.5 Publication of results;

3.2 Literature review and collection of existing statistics and estimations at global, European, and country levels (sub-task T1.2.1)

3.2.1 Literature review

The literature review analyses the methodologies developed to estimate AM use in the different countries and LPSs. The review covers the main regional contexts and types of animal production with a particular focus on the countries and livestock species in the Roadmap case studies.

The ROADMAP Country Leaders provide the Task Leader with an English version (or a summary) of the methodological guidelines for official reporting on veterinary AMU in the respective countries, and any other relevant publication that investigates the assessment of veterinary AM use.

3.2.2 AM use statistics

Available statistics of AMU at global, European, and country levels are collected. The aim of statistic data collection at the country level is to compare AMU and AMU trends by species for the main food producing animals in the Roadmap countries.

The ROADMAP Country Leaders provide the Task Leader with an English version of the last five national reports on AMU issued by their own countries. Where no official English version of the national reports is available, the Country Leaders provide summaries of the official annual reports in English together with tables of AMU.

3.3 Characterization of case studies' livestock production systems and identification of data available (sub-task T1.2.1)

Based on the analysis reported in §3.1.1, the aim of quantifying current AMU in different production systems can rely on official data sources only to a limited extent and the contribution of ROADMAP partners and case study leaders to data supply is therefore crucial.

The ROADMAP Project's research activity is based on 26 case studies (CSs) differentiated per animal species, type of products, and livestock production systems, as indicated in the below scheme:

- Case-study cluster 1, intensive and conventional production systems;
- Case-study cluster 2, alternative production systems:
    - Organic and/or sustainable labels;
    - Intensive systems with quality labels, such as welfare or AM-free standards;
- Case-study cluster 3, marginal production systems:
    - Marginalized rural areas (with poor access to veterinary services, etc.);
    - Marginal animals and/or workers (not considered as a priority in the farm management);
    - Marginal regulatory framework (poor implementation, relevant presence of informal drug distribution channels, etc.).

Table 2 – ROADMAP case studies

Species	*CS intensive production systems*	*CS alternative production systems*	*CS marginal production systems*	***Total case studies***
Pig	1. Belgium 2. Denmark 3. France 4. Italy	5. Denmark 6. France 7. Italy 8. Switzerland	9. The Netherlands	**9**
Poultry	10. France 11. Italy 12. Sweden	13. France 14. Sweden	15. The Netherlands 16. Mozambique 17. Vietnam	**8**
Dairy	18. Sweden 19. France	20. Denmark 21. France 22. Sweden	23. United Kingdom	**6**
Beef	-	24. Switzerland	25. Belgium 26. United Kingdom	**3**
Total case studies	**9**	**10**	**7**	**26**

The specific T1.2.2 objective is to achieve a technical-economic characterization of the farms involved the Roadmap CSs, to deepen the knowledge on the application of biosecurity, animal health and welfare practices favouring a reduced use of antibiotics, and to obtain information on the type of data related to AMU in the farms that can be delivered by the different CSs depending on the existing data sources and on the available project resources.

A questionnaire (see Annex 1) is then delivered to the CS leaders to collect the following information about the CS farms:

- relevant characteristics of the CS farms;
- integration of the CS farms with the upstream and the downstream industries and services;
- animal welfare standards, biosecurity, health management and accession to veterinary services in the CS farms;
- collectable data on AMU in the CS farms.

The questionnaire is aimed at:

- achieving an insight of the 26 Roadmap CSs and their context that could support data collection for the assessment of antimicrobial use in the different livestock production systems and, in case, for other Roadmap tasks;
- giving information on types of data on antimicrobial use in CS farms that can be provided, given the actual availability of data and Roadmap resources.

The questionnaire is intended to be filled in by CS leaders without need to visit or interview farmers or other stakeholders. The assumption is that CS leaders already have a proper knowledge of the farms involved in the CS. Precise quantitative information is not required at this stage, it is enough to answer the questionnaire with approximate figures and qualitative information. Information on the current knowledge gaps (e.g. to explain briefly the reason why a given question cannot be answered) is also very useful.

The information collected from CS leaders is used to characterize the CS farms with the aim of investigating the levels of AM use and designing the case study analysis in the following T1.2 subtasks.

A second brief questionnaire (see Annex 2) is also elaborated to collect additional information on the availability of data on antimicrobial (AM) use in the farms of the ROADMAP case studies (CSs). This second question has slightly different versions depending on the livestock species concerned by the CS: only the version for pigs has been annexed to this report.

The main objectives of the second questionnaire are:

- setting up the data collection for Task T1.2 in order to carry out a comparative analysis on the use of AMs between the different pig production systems and between the different countries;

- provide information to the other ROADMAP Tasks and Work Packages regarding the type of data available from the case studies

3.4 Collection and analysis of AM use data in case studies' farms (sub-task T1.2.3)

The information achieved with subtask T1.2.2 allows collection and analysis of CS farm data on AM consumption. This subtask is developed into three stages:

- Designing the CS farm data collection and analysis;
- CS farm data collection;
- CS farm data elaboration and analysis.

The design of CSs' data collection and analysis is elaborated in cooperation with the CS Leaders, based on the type of data and the amount of Roadmap resources available. The results of subtask T1.2.2 indicate the level of analytical detail of the investigation in the different CSs: such decisions is also influenced by the needs of coordination with data collection of the other ROADMAP tasks.

3.5 Report writing, deliverable finalization (November 2020 – May 2021) and publication of results (sub-tasks T1.2.4 and T1.2.5)

The structure of the final T1.2 report and deliverable D1.2 will be defined with the design of the T1.2.3 data collection and analysis. A strategy for results' publication will follow.

4 Evolutionary analysis of the regulatory and institutional context (Task T1.3)

4.1 Background and objectives of the Task

4.1.1 The current evolution of the European policy for AMR control in the livestock industry

The leading intergovernmental organizations and the EU have launched policy strategies that target a more prudent use of AMs in both the human and the veterinary medicine to face the rising threat of AM resistance [59–61]. This includes more attentive monitoring on the use of AMs in humans and animals, the spread of infections from resistant bacteria, and the presence of resistant zoonotic and commensal bacteria in animal farms and along the food supply chain.

The objective of the EU policy is not to phase out AMs from animal production but guide farmers to a more cautious utilization by reducing as much as possible prophylactic and metaphylactic treatments and controlling tighter the prescription, marketing, storage and administration of these medicines, especially the active principles of critical importance for human health. To achieve this partial decoupling of livestock farming from AMU, the EU is deploying a mix of measures that include: (i) new stricter regulations on AMU and traceability, (ii) the monitoring of AMU and presence of AM resistant microorganisms in farms, environment, and the supply chain, (iii) awareness campaigns addressed to farmers, other stakeholders and the general public, (iv) incentives to the improvement of biosecurity, alternative treatments in farms, and the development of private standards related to AM use in livestock production, (vi) training for farmers and veterinarians, (vii) finance to scientific research, (viii) and coordinated initiatives at the global level [45,59,62].

The current situation of AM policies at the level of the EU Member States (MSs) is however quite inhomogeneous: in some countries, the national legislation is already complying with the new EU measures and is even stricter for some aspects, while other countries are likely to have problems for respecting the first deadlines for implementation expiring in 2022.

4.1.2 Specific objectives of the Task

The Task T1.3 maps the existing regulatory framework on the use of AMs in the livestock farms of Europe and selected non-European countries, and its current evolution, including the development of private standards. T1.3 examines:

- the orientations and the global policy strategies for a more prudent AMU in livestock farming indicated by the international organizations (WHO, OIE, FAO, World Bank, OECD, etc.);
- the relevant national regulations and policies on veterinary AMU outside the European Union;
- the EU and Member States' legislation and policies;
- the development of private standards in the countries involved in the ROADMAP project and relevant experiences on the issue in other countries within and outside Europe;
- qualitative evaluations on the impacts and effectiveness of the different policy approaches and types of measures.

The main sources of information and data are the scientific literature and the project's case studies, also through surveys and key respondent interviews.

The objective of T1.3 is, in a first stage, to carry out the tasks T1.3.1 – T1.3.4 by starting with the collection of information.

4.2 Literature review

The literature review collects and analyse scientific materials related to:

- the studies and the discussion that accompanied the elaboration of the current global, EU, and national policy strategies for a more prudent AMU in livestock farming;
- the analyses and the on-going debate on the effectiveness and the evolution of such policies and legislation;
- the analyses and the debate on the application of private labels certifying claims related to animal products obtained without the use of AMs;

The ROADMAP Country Leaders provide the T1.3 Leader with the available scientific literature regarding their own country and other relevant contexts.

4.3 Collecting information on national legislation and policies

The ROADMAP Country Leaders provide the T1.3 leader with the information concerning their own countries detailed in the outline of a specific template report (see Annex 3).

The T1.3 leader collects the information related to the EU and the AMU reduction strategies of the intergovernmental organizations concerned and from relevant non-European countries. For the non-European countries, the information collected related to points concern the same subjects of the European legislation indicated in the annexed outline.

4.4 Qualitative evaluations on the impacts and effectiveness of the different policy approaches and types of measures

The qualitative evaluation related to T1.3.5 starts after the data collection. The evaluation methodology includes assessments on the following aspects:

- efficacy resulting from reduction of AMU and AMR resulting from specific monitoring data;
- coherence of national strategies with guidelines of international organizations and the EU (only for the EU member states);
- relevance of measures deployed resulting from comparison between countries;
- capacity of implementation of the different measures resulting from the information collected.

5 Systemic analysis of stakeholders' behaviours in the animal products supply chain and the animal health system (T1.4)

5.1 Background, objectives and general strategy of the Task

In T1.4, we will perform a structural-functional analysis of the antimicrobial decision-systems. We combine the analytical framework based on the agricultural innovation systems approach and the value chain approach. We proceed in three steps

- Step 1: descriptive stakeholder mapping: identifying actors, roles and interactions
    - Based on key informant interviews
- Step 2: further structural analysis: Identifying infrastructures, soft institutions, capabilities, and market structures
    - Based on stakeholder interviews, document analysis and secondary data analysis; linking institutions (T1.3) to actors and interactions
- Step 3: functional analysis: how do structures determine/affect the functioning?
    - Based on stakeholder interviews, document analysis, participatory observation, focus groups

5.2 Type of information and data needed

The information that is needed is a description of all actors, interactions and further structural characteristics of the antimicrobial decision systems. As explained above, this information is collected – and analysed in three different steps.

Step 1. Descriptive stakeholder mapping [58,63]. In this stage, information is needed on (1) actors and (2) interactions between actors.

- All actors need to be identified, their role described, and the actors need to be described in terms of their influence and interest.
    - The influence refers to the potential influence they have on AMU and AMR. This influence should be described according to influence resulting from
        - **Power:** ability to make another stakeholder do something because it has:
            - Coercive power: stakeholder can use force, threat, …
            - Instrumental/utilitarian: stakeholder can use material or financial incentives
            - Normative: stakeholder can use symbolic resources e.g. prestige, love, friendship, esteem, social relationship
        - **Legitimacy:** ability to make another stakeholder do something because that other stakeholder perceives it as an entity whose actions are desirable and who generally behaves according to socially accepted norms, values and beliefs

        - **Urgency:** ability to make another stakeholder do something because its claims call for immediate action
    - The interest refers to the degree to which AMU and AMR affects each actor's personal goals and expectations. It should be described in general terms and whether the basis is financial and/or non-financial.
- All interactions between actors should be identified and described, first in general terms, then according to the following information
    - **The direction of the interaction**: from one to the other, in both directions, or rather through a network with more than 2 actors
    - **Strength of interaction**: strong or weak
    - **Formality**: formal means there is some formal institution (public regulation or private standard governing the interaction (the fact *that* the interaction exists and/or *how* the interaction is), informal means that there is not such a thing
    - **Flow**: what flows between the actors
        - Material: products (which products), services
        - Immaterial: advice, knowledge, data, mere influence
        - Financial: money

Step 2. Further structural description of the antimicrobial decision system. The information that is needed here refers to the other characteristics of the antimicrobial decision system that are deemed important, based on the agricultural innovation systems approach and the value chain approach. It refers to

- Identification of market characteristics (value chain governance & organization): positions of and relationships between market parties, competition level, vertical integration, business models
- Identification of capabilities: learning capacities, organisational skills, innovativeness, …
- Identification of infrastructures: physical infrastructure, knowledge infrastructure, financial infrastructure, …
- Identification of soft institutions: rules, norms, habits, routines, …
- Quantitative description of market structure: numbers, concentration, economic indicators, …
- Linking hard institutions (public regulation and private standards; T1.3) to actors and structures

Step 3. Functional analysis. This step is more analysis and should be based on the previous steps. This step requires no additional information but will perform analysis based on the information available from the previous steps.

5.3 Data collection strategy

This task will heavily rely on: (1) key-informant interviews; (2) stakeholder in-depth interviews; (3) data collection from grey literature, scientific literature and secondary databases; (4) focus groups; (5) descriptive field notes taken during Pillar 2 and Pillar 3 activities.

Key informant interviews: key informants are people from whom we expect to learn the most so that we produce maximum knowledge with minimum number of interviews. These interviews will be rather semi-structured, centered around an interview guide probing at certain attributes. Examples of key-informants are:

- Researchers
- Advisors
- People working at associations of farmers, vets, pharmaceutical companies
- Farmers
- Vets

Stakeholder in-depth interviews: these are interviews with individual members of all identified actor types. For stakeholder in-depth interviews, it is more important that all different stakeholder represent a certain variety of viewpoints, not that all respondent can be regarded as a key-informant. These interviews are also more in-depth.

Focus groups. Focus groups are groups of people that interact with each other and with the facilitator (researcher) around a certain topic. Focus groups differ from group interviews in that there is more interaction and less a one-way communication from researcher to respondents. The facilitator observes the interaction rather than asking direct questions.

Sampling procedure for key-informant interviews, stakeholder in-depth interviews and focus groups: combination of non-probability sampling methods:

- Convenience sampling: “easy to reach”
- Snowball sampling: “ask respondent to refer to others”
- Judgmental sampling: “contact respondents based on certain characteristics”
- Add a form of quota sampling: try to reach out to respondents from stakeholder groups/roles from which you haven’t interviewed any.
- Sample size: ideally based on saturation: stop interviewing when your last respondent (provided you used different sampling methods and entry points) does not provide new information (does not add anything relevant to the existing stakeholder map)

Data from (grey) literature and secondary databases. Depending on availability and accessibility, also data from grey literature can be used, and data from secondary databases (e.g., on production, structural characteristics of the value chains, economic indicators, …) will have to be collected to perform a structural-functional analysis.

Descriptive field notes from pillar 2 and 3. Pillar 2 adopts a much more participator approach to co-creating solutions, based on a participatory assessment of the antimicrobial decision system. Additional data in the form of descriptive field notes will be collected for further analysis in WP 1.

5.4 Methods for data elaboration and analysis

Data analysis will be performed using thematic analysis. For the thematic analysis a mixed deductive-inductive approach will be used. A set of deductive codes will be derived from our conceptual frameworks (agricultural innovation system approach and value chain approach), but there will be room for inductive codes build on the available data.

Doing coding is involves coding the interview transcripts thematically, either manually on printouts, or with software (e.g. Nvivo). There are basically three types of coding:

- Open – descriptive labels allocated to sections of data to make sense of the data. This is more a form of data cleaning and data preparation to make it ready for analysis through axial and selective coding.
- Axial – identifying relationships between open codes
- Selective – building a story that connects the categories

The coding will ideally be performed in three iterative steps.

- Stage 1: Initial read
    - Read text as a whole and make notes at end
    - Look for what it is about
    - Major themes
    - Unusual issues, events etc.
    - Group cases (respondents) into types or categories
- Stage 2: Read again & code the text
    - Systematically mark the text (underline, circle, highlight or code using software) & indicate what chunks of text are about – open coding
    - Identify relationships between the codes (e.g. sub-themes) – axial coding
    - Marginal notes/annotations
- Stage 3: Review the coding
    - Review the codes
    - Eliminate repetition and similar codes (combine)
- Stage 4: Interpretation
    - Describe interactions, connections and build results.

6 Integrated WP1-WP2 systemic identification of socio-technical lock-ins and priorities for actions (Task T1.5)

This task merges the results of the two WPs involved in Pillar 1 (Diagnosis) with the aim of categorising and creating a hierarchy of the socio-technical lock-ins towards a reduced AMU identified at both the micro (farm) and macro (the food-supply chain and the animal health system, including the veterinary drug market) levels and indicate priorities for the initiatives to be designed within Pillars 2 and 3.

The Task breakdown includes:

(1) synthesis of WP1 results;

(2) synthesis of WP2 results;

(3) integrated systemic identification and hierarchisation of socio-technical lock-ins to be removed at both the micro and the macro level, also using information and data provided by the WP3 and 4 Living Labs;

4) identification of priorities for action.

T1.5 will be developed after the conclusion of WP1 and WP2 research activities in a later stage of the ROADMAP Project. The methodology will be detailed as soon as WP1 and WP2 researchers have enough elements to produce such outcome.

7 References

[1] J. Hockenhull, A.E. Turner, K.K. Reyher, D.C. Barrett, L. Jones, S. Hinchliffe, H.J. Buller, Antimicrobial use in food-producing animals: a rapid evidence assessment of stakeholder practices and beliefs., Vet. Rec. 181 (2017) 510. doi:10.1136/vr.104304.

[2] J.-M. Meynard, F. Charrier, M. Fares, M. Le Bail, M.-B. Magrini, A. Charlier, A. Messéan, Socio-technical lock-in hinders crop diversification in France, Agron. Sustain. Dev. 38 (2018) 54. doi:10.1007/s13593-018-0535-1.

[3] G. Plumecocq, T. Debril, M. Duru, M.-B. Magrini, J.P. Sarthou, O. Therond, The plurality of values in sustainable agriculture models: diverse lock-in and coevolution patterns, Ecol. Soc. 23 (2018) art21. doi:10.5751/ES-09881-230121.

[4] W.B. Arthur, Competing Technologies, Increasing Returns, and Lock-In by Historical Events, Econ. J. 99 (1989) 116. doi:10.2307/2234208.

[5] E. Shove, Beyond the ABC: Climate Change Policy and Theories of Social Change, Environ. Plan. A Econ. Sp. 42 (2010) 1273–1285. doi:10.1068/a42282.

[6] D. Evans, Blaming the consumer – once again: the social and material contexts of everyday food waste practices in some English households, Crit. Public Health. 21 (2011) 429–440. doi:10.1080/09581596.2011.608797.

[7] C. Lamprinopoulou, A. Renwick, L. Klerkx, F. Hermans, D. Roep, Application of an integrated systemic framework for analysing agricultural innovation systems and informing innovation policies: Comparing the Dutch and Scottish agrifood sectors, Agric. Syst. 129 (2014) 40–54. doi:10.1016/j.agsy.2014.05.001.

[8] L. Klerkx, B. Van Mierlo, C. Leeuwis, Evolution of systems approaches to agricultural innovation: Concepts, analysis and interventions, in: Farming Syst. Res. into 21st Century New Dyn., Springer Netherlands, 2012: pp. 457–483. doi:10.1007/978-94-007-4503-2_20.

[9] J.A. Turner, L. Klerkx, K. Rijswijk, T. Williams, T. Barnard, Systemic problems affecting co-innovation in the New Zealand Agricultural Innovation System: Identification of blocking mechanisms and underlying institutional logics, NJAS - Wageningen J. Life Sci. 76 (2016) 99–112. doi:10.1016/j.njas.2015.12.001.

[10] E. Kebebe, A.J. Duncan, L. Klerkx, I.J.M. de Boer, S.J. Oosting, Understanding socio-economic and policy constraints to dairy development in Ethiopia: A coupled functional-structural innovation systems analysis, Agric. Syst. 141 (2015) 69–78. doi:10.1016/j.agsy.2015.09.007.

[11] L. Klerkx, N. Aarts, C. Leeuwis, Adaptive management in agricultural innovation systems: The interactions between innovation networks and their environment, Agric. Syst. 103 (2010) 390–400. doi:10.1016/j.agsy.2010.03.012.

[12] C. Rojo-Gimeno, J. Dewulf, D. Maes, E. Wauters, A systemic integrative framework to describe comprehensively a swine health system, Flanders as an example, Prev. Vet. Med. 154 (2018) 30–46. doi:10.1016/J.PREVETMED.2018.02.017.

[13] D.H. Taylor, Value chain analysis: an approach to supply chain improvement in agri-food chains, Int. J. Phys. Distrib. Logist. Manag. 35 (2005) 744–761. doi:10.1108/09600030510634599.

[14] G. Gereffi, J. Humphrey, T. Sturgeon, The governance of global value chains, Rev. Int. Polit. Econ. 12 (2005) 78–104. doi:10.1080/09692290500049805.

[15] N. Terpend, Guide pratique de l'approche filière. Le cas de l'approvisionnement et de la distribution des produits alimentaires dans les villes, Rome, 1997. http://www.fao.org/3/a-x6991f.pdf (accessed November 14, 2017).

[16] M. Aragrande, O. Argenti, Studying food supply and distribution systems to cities in developing countries and countries in transition: methodological and operational guide (revised version), Rome, 2001. http://www.fao.org/3/a-x6996e.pdf (accessed November 14, 2017).

[17] J.-L. Rastoin, G. Ghersi, Le système alimentaire mondial concepts et méthodes, analyses et dynamiques, Quae, Versailles, 2010. http://www.quae.com/en/r966-le-systeme-alimentaire-mondial.html (accessed October 11, 2018).

[18] L. Malassis, G. Ghersi, Initiation à l'économie agro-alimentaire, Hatier, Paris, 1992. http://www.bibliotheque.auf.org/index.php?lvl=notice_display&id=291 (accessed June 13, 2016).

[19] L. Temple, F. Lançon, F. Palpacuer, G. Paché, Actualisation du concept de filière dans l'agriculture et l'agroalimentaire, Économies et Sociétés. AG (2011) 1785–1797. https://halshs.archives-ouvertes.fr/hal-00802690/ (accessed November 14, 2017).

[20] A. Muljono, A.G.J. Velthuis, J. Rushton, H. Hogeveen, A Quantitative value chain analysis of dutch Broiler industry with regards to the use antibiotics, (2012).

[21] S. Achchuthan, R. Kajananthan, A Study on Value Chain Analysis in Dairy Sector Kilinochchi District, Sri Lanka, Glob. J. Manag. Bus. Res. Type Year. 12 (2012). https://globaljournals.org/GJMBR_Volume12/1-A-Study-on-Value-Chain-Analysis.pdf (accessed November 14, 2017).

[22] J. Donovan, M. Cunha, S. Franzel, A. Gyau, D. Mithöfer, Guides for value chain development: a comparative review, CTA & World Agroforestry Centre, Wageningen (NL), 2013. https://publications.cta.int/media/publications/downloads/1746_PDF.pdf (accessed November 15, 2017).

[23] K.M. Rich, R.B. Ross, A.D. Baker, A. Negassa, Quantifying value chain analysis in the context of livestock systems in developing countries, Food Policy. 36 (2011) 214–222. doi:10.1016/j.foodpol.2010.11.018.

[24] B.G. Smith, Developing sustainable food supply chains., Philos. Trans. R. Soc. Lond. B. Biol. Sci. 363 (2008) 849–61. doi:10.1098/rstb.2007.2187.

[25] T. Marsden, J. Banks, G. Bristow, Food supply chain approaches: Exploring their role in rural development, Sociol. Ruralis. 40 (2000) 424–438. doi:10.1111/1467-9523.00158.

[26] M. Labonne, Sur le concept de la filière en économie agro-alimentaire, in: D. Kermel-Torrès, P.-J. Roca, M. Bruneau, G. Courade (Eds.), Terres, Comptoirs Silos Des Systèmes Prod. Aux Polit. Aliment., ORSTOM, Paris, 1987: pp. 137–149. http://www.documentation.ird.fr/hor/fdi:24865 (accessed November 14, 2017).

[27] P. Raikes, M. Friis Jensen, S. Ponte, Global commodity chain analysis and the French filière approach: comparison and critique, Econ. Soc. 29 (2000) 390–417. doi:10.1080/03085140050084589.

[28] C. Lamine, S. Bellon, Conversion to organic farming: a multidimensional research object at the crossroads of agricultural and social sciences. A review, Agron. Sustain. Dev. 29 (2009) 97–112. doi:10.1051/agro:2008007.

[29] E. Dimara, A. Petrou, D. Skuras, The socio-economics of niche market creation: A social ecology

paradigm for the adoption of organic cultivation in Greece, Int. J. Soc. Econ. 30 (2003) 219–235. doi:10.1108/03068290310460134.

[30] H. El Bilali, The Multi-Level Perspective in Research on Sustainability Transitions in Agriculture and Food Systems: A Systematic Review, Agriculture. 9 (2019) 74. doi:10.3390/agriculture9040074.

[31] S. Wigboldus, L. Klerkx, C. Leeuwis, M. Schut, S. Muilerman, H. Jochemsen, Systemic perspectives on scaling agricultural innovations. A review, Agron. Sustain. Dev. 36 (2016) 1–20. doi:10.1007/s13593-016-0380-z.

[32] B. Elzen, M. Barbier, M. Cerf, J. Grin, Stimulating transitions towards sustainable farming systems, in: Farming Syst. Res. into 21st Century New Dyn., Springer Netherlands, 2012: pp. 431–455. doi:10.1007/978-94-007-4503-2_19.

[33] D.A. Vermunt, S.O. Negro, F.S.J. Van Laerhoven, P.A. Verweij, M.P. Hekkert, Sustainability transitions in the agri-food sector: How ecology affects transition dynamics, Environ. Innov. Soc. Transitions. 36 (2020) 236–249. doi:10.1016/j.eist.2020.06.003.

[34] F.W. Geels, Technological transitions as evolutionary reconfiguration processes: A multi-level perspective and a case-study, Res. Policy. 31 (2002) 1257–1274. doi:10.1016/S0048-7333(02)00062-8.

[35] F.W. Geels, J. Schot, Typology of sociotechnical transition pathways, Res. Policy. 36 (2007) 399–417. doi:10.1016/j.respol.2007.01.003.

[36] V.F. Jensen, E. Jacobsen, F. Bager, Veterinary antimicrobial-usage statistics based on standardized measures of dosage, Prev. Vet. Med. 64 (2004) 201–215. doi:10.1016/j.prevetmed.2004.04.001.

[37] H. Lardé, S. Dufour, M. Archambault, D. Léger, D. Loest, J.-P. Roy, D. Francoz, Assignment of Canadian Defined Daily Doses and Canadian Defined Course Doses for Quantification of Antimicrobial Usage in Cattle, Front. Vet. Sci. 7 (2020) 10. doi:10.3389/fvets.2020.00010.

[38] S. Kasabova, M. Hartmann, N. Werner, A. Käsbohrer, L. Kreienbrock, Used Daily Dose vs. Defined Daily Dose—Contrasting Two Different Methods to Measure Antibiotic Consumption at the Farm Level, Front. Vet. Sci. 6 (2019) 116. doi:10.3389/fvets.2019.00116.

[39] Z. WU, Antimicrobial use in food animal production: situation analysis and contributing factors, Front. Agric. Sci. Eng. 5 (2018) 301. doi:10.15302/J-FASE-2018207.

[40] N. Werner, S. McEwen, L. Kreienbrock, Monitoring Antimicrobial Drug Usage in Animals: Methods and Applications, in: Antimicrob. Resist. Bact. from Livest. Companion Anim., American Society of Microbiology, 2018: pp. 569–594. doi:10.1128/microbiolspec.arba-0015-2017.

[41] R. Merle, B. Meyer-Kühling, Sales data as a measure of antibiotics usage: Concepts, examples and discussion of influencing factors, Vet. Med. Sci. 6 (2020) 154–163. doi:10.1002/vms3.205.

[42] L.E. Redding, H. Grunwald, C. Melofchik, P. Meily, A. Henry, D. Stefanovski, Comparison of animal daily doses and days of therapy for antimicrobials in species of veterinary importance, Prev. Vet. Med. 176 (2020) 104942. doi:10.1016/j.prevetmed.2020.104942.

[43] D. Góchez, M. Raicek, J.P. Ferreira, M. Jeannin, G. Moulin, E. Erlacher-Vindel, OIE annual report on antimicrobial agents intended for use in animals: Methods used, Front. Vet. Sci. 6 (2019). doi:10.3389/fvets.2019.00317.

[44] EMA-ESVAC, Sales of veterinary antimicrobial agents in 31 European countries in 2017, Trends

from 2010 to 2017, Ninth ESVAC report, London, 2019. https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2017_en.pdf (accessed March 11, 2020).

[45] European Parliament and the Council, Regulation (EU) No 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance), 2019. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006&from=EN (accessed September 24, 2019).

[46] European Commission, Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (2013/652/EU), 2013.

[47] EMA-ESVAC, Guidance on provision of data on antimicrobial use by animal species from national data collection systems Guidance on provision of data on antimicrobial use by animal species from national data collection systems Table of contents, London, 2018. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500224492.pdf.

[48] EMA-ESVAC, Principles on assignment of defined daily dose for animals (DDDvet) and defined course dose for animals (DCDvet), London, 2015. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/06/WC500188890.pdf.

[49] EMA-ESVAC, Defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet): European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), London, 2016. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/04/WC500205410.pdf.

[50] WHO, Introduction to Drug Utilization Research, World Health Organization , Oslo, 2003. http://digicollection.org/hss/en/p/printable.html (accessed August 19, 2020).

[51] AACTING-network, Description of existing monitoring systems for collection, analysis, benchmarking, and reporting of farm-level veterinary antimicrobial usage - Version 2.1_2020-05-19, 2020. www.aacting.org.

[52] SDa, Usage of Antibiotics in Agricultural Livestock in the Netherlands in 2018. Trends and benchmarking of livestock farms and veterinarians, Utrecht, 2019.

[53] BelVet-SAC, Belgian Veterinary Surveillance of Antibacterial Consumption. National consumption report 2018, Bruxelles, 2018.

[54] DANMAP, Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark-DANMAP 2018, Lyngby - Copenhagen, 2019. www.danmap.org.

[55] Anses-ANMV, Suivi des ventes de médicaments vétérinaires contenant des antibiotiques en France en 2018, Maisons-Alfort, 2019.

[56] UK-VARSSR, UK Veterinary Antibiotic Resistance and Sales Surveillance Report - UK VARSSR 2018, New Haw, Addlestone, 2019. www.nationalarchives.gov.uk/doc/open-government-licence/version/3/oremailPSI@nationalarchives.gov.uk.ThispublicationisavailableatwwwgovUK/government/collections/veterinary-antimicrobial-resistance-and-sales-surveillance.

[57] Ministero della Salute - Direzione generale della sanità animale e dei farmaci veterinari, Dati di vendita dei medicinali veterinari contenenti agenti antimicrobici. Trend in Italia - Anno 2016,

Roma, 2018. http://www.salute.gov.it/imgs/C_17_pubblicazioni_2780_allegato.pdf (accessed June 21, 2019).

[58] M. Sargenti, M. Capuccella, G. Perugini, N. Aconiti Mandolini, G. Filippini, A. Baiguini, A. Vaccaro, G. Pelagalli, F. Marinelli, L. Nespeca, P. Pierucci, Analisi descrittiva sul consumo di antibiotici nei settori zootecnici della Regione Marche: anno 2018, Sanità Pubblica Vet. Anno 2019 (2019). http://spvet.it/archivio/numero-115/701.html (accessed August 31, 2020).

[59] European Commission, A European One Health Action Plan against Antimicrobial Resistance (AMR), Brussels, 2017. https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf (accessed August 19, 2018).

[60] European Commission, PROGRESS REPORT 2017 EU AMR ACTION PLAN - Last update: Q2 2019, (2019) 24.

[61] European Commission, Commission Notice — Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04), 2015. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1569342758046&uri=CELEX:52015XC0911(01) (accessed September 24, 2019).

[62] European Parliament and the Council, REGULATION (EU) 2019/4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing, The European Parliament an the Council, Brussels, 2019.

[63] J.M. Bryson, What to do when Stakeholders matter, Public Manag. Rev. 6 (2004) 21–53. doi:10.1080/14719030410001675722.

8 Annexes

Annex 1 - Questionnaire on the characteristics of case studies' farms and on the availability of data on antimicrobial use

ROADMAP - TASK 1.2

Assessment of antimicrobial use in the different livestock production systems

Questionnaire on the characteristics of case studies' farms and on the availability of data on antimicrobial use

Sections

General notes and deadline

1. Case study identification
2. Information on case study farms
3. Information on case study farms' integration with upstream and downstream industries
4. Information on animal welfare standards, biosecurity, health management and veterinary services on case study farms.
5. Information on the type of data about antimicrobial use in the case study farms that can be given to the Roadmap project
6. Additional relevant information and comments on the case study farms and the questionnaire

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General notes and deadline

The main objectives of this questionnaire are:

I. to achieve an insight of the 26 Roadmap case studies (CSs) and their context which could support data collection for the Roadmap task T1.2 (Assessment of antimicrobial use in the different livestock production systems) and, in case, for other Roadmap tasks;
II. to receive information on the types of data on antimicrobials use in CS farms that can be provided by CS leaders, given the actual availability of data and Roadmap resources (Section 5).

The questionnaire is intended to be filled by CS leaders without need to visit or interview farmers or other stakeholders. The assumption is that CS leaders already have a proper knowledge of the farms involved in the CS.

It is not necessary to provide precise quantitative information, approximate figures and qualitative information are acceptable. However, explaining the reason why a question cannot be answered will provide very useful information.

For further details, please contact: massimo.canali2@unibo.it.

DEADLINE: Please, fill in the questionnaire by next 19 January 2020.

1 Case study identification

1.1 Case study (CS) coordinates:

Group (intensive/label/marginal): **Country:** **Animal species:**

1.2 Provide a brief summary information of the CS, explaining the main reasons for classification within this group:

2 Information on case study farms

1.3 Provide information on how many farms are included in the CS:

1.4 Provide information on the geographic distribution of the CS farms (homogeneously distributed in the country, concentrated in some regions/areas, etc. …, include/attach a map where possible):

1.5 Provide information on the main marketed livestock products of the CS farms:

1.6 Provide information on relevance of the CS farms with respect to the total farms operating in the same sector within the country (CS farms/total farms; CS farms livestock heads/total livestock heads; CS farm production/total production; etc.):

1.7 Provide information on the types of businesses of the CS farms (family holdings, cooperatives, companies, etc.):

1.8 Provide information on the volumes of annual livestock production in the CS farms (volumes of production in individual farms):

1.9 Provide information on the value of annual livestock production in the CS farms (production value in individual farms):

1.10 Provide information on the number of livestock heads of the CS farms in the different live-stock categories (livestock heads in individual farms):

1.11 Provide information on the number of livestock heads per working unit employed in the CS farms (livestock heads per working unit in individual farms):

1.12 Provide information on the level of specialization of the CS farms (relevance of crop production and livestock production from other species in the total production value of individual farms):

1.13 Provide information on the size of farmland for CS farms:

1.14 Provide information on the herd management systems in the CS farms:

1.15 Provide information on the feeding systems and related relevance of farm feed production in the CS farms:

1.16 Provide information on the manure management systems and related relevance of farm land in the CS farms:

1.17 Provide information on animal lodging in the CS farms (indoor/outdoor/mixed; slatted floor/mixed/litter/other; etc.):

1.18 Additional information and comments on CS farms and livestock production system characteristics:

3 Information on case study farms' integration with upstream and downstream industries

1.19 Provide information on the CS farms relevant links and contracts with upstream industries and services:

Genetics:
Animal feeding:
Veterinary services and pharmaceuticals:
Technical assistance:
Other upstream industries and services:

1.20 Provide information on the CS farms relevant links and contracts with downstream industries and services (main buyers and type of contracts):

1.21 Provide information on labelled production and special product standards in the CS farms:

Organic products:
Geographical indications:
Other local labels:
Quality control schemes:
Special features of animal feed:
Special features qualities of products:
GMO free:
Extra measures in ethical standards:
Extra measures in animal welfare standards:
Extra measures in environmental standards:
Produced without the use of antibiotics:
Other types of labels:

1.22 Additional information and comments on CS farms and livestock production systems integration with upstream and downstream industries:

4 Information on animal welfare standards, biosecurity, health management and veterinary services on case study farms.

1.23 Provide information on the animal welfare standards found in the CS farms:

1.24 Provide information on what could be done to improve animal welfare in the CS farms:

1.25 Provide information on application of biosecurity requirements and practices in the CS farms:

1.26 Provide information on what could be done to improve biosecurity in the CS farms:

1.27 Provide information on the organization of the private and public veterinary services supporting the CS farms:

1.28 Provide information on what could be done to improve the organization of the private and public veterinary services supporting the CS farms:

1.29 Additional information and comments on biosecurity, health management, and veterinary services on the CS farms:

5 Information on the type of data about antimicrobial use in the case study farms that can be given to the Roadmap project

1.30 Give information on how you can provide data on AM use in the CS farms (include the time span of the data which can be provided in the information given):

Data from published statistics or open access databases:
Data from public databases with restricted access (e.g. national/local veterinary databases):
Data from private databases (e.g. producer associations, technical assistance services, veterinary private services, etc.):
Data to be directly collected from farms or other data providers through questionnaires and interviews:

1.31 Give information on the type of data on AM use in the CS farms that you can provide (include the time span of the data which can be provided in the information given):

Aggregate data on AM use per farm, farm category, and livestock category (e.g.: calves, heifers, adult milk cows, etc.; sows, piglets, weaners, finishers, etc.; broilers, etc.):
Data on AM use in single farms per livestock category:
Data on AM use per active principle in mg/kg of farmed animal biomass, or daily defined doses (DDDs), or defined course doses (DCDs):
Data on prophylactic, metaphylactic, and therapeutic AM use, and individual and group treatments:
Data on AM use in oral (boluses, tablets, oral pastes, oral powders, oral solutions, and premixes), parenteral (injections), intramammary (in lactating and dry cows), and intrauterine forms:

1.32 Additional information and comments on providable data on antimicrobial use:

6 Additional relevant information and comments on the case study farms and the questionnaire

1.33 Additional relevant information and comments on the CS farms and the questionnaire:

Annex 2 - Collection of additional information on the availability of data on the use of antimicrobials in the ROADMAP case study farms

ROADMAP - TASK 1.2

Assessment of antimicrobial use in the different live-stock production systems

Collection of additional information on the availability of data on the use of antimicrobials in the ROADMAP case study farms

- PIG CASE STUDIES -

(version 2020-03-18)

Following decisions agreed in the ROADMAP Assembly of last February and in the ROADMAP Executive Committee meeting of last 2 March, this brief questionnaire has been elaborated to collect additional information on the availability of data on antimicrobial (AM) use in the farms of the ROADMAP case studies (CSs).

This questionnaire is particularly addressed to the CSs where data on AM use and other farm data are stored and can be extracted from a database. For the CSs where data on AM use can only be collected directly from farmers through questionnaire interviews, just the CS identification is requested by answering the question 1 and the question 2.

The main objectives of the questionnaire are:

(1) setting up the data collection for Task T1.2 in order to carry out a comparative analysis on the use of AMs between the different pig production systems and between the different countries;

(2) provide information to the other ROADMAP Tasks and Work Packages regarding the type of data available from the case studies.

Filled-in questionnaires should be sent back by e-mail to: massimo.canali2@unibo.it, by the 31th March 2020.

QUESTIONNAIRE CONTENTS

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1 Case study coordinates:

Group (intensive/label/marginal): Country: Animal species: **Pigs**

2 Availability of data on AM use in the case study farms:

2.1	Data on AM consumption in the case study farms are stored in a database (in this case, please, fill in all the questionnaire);	☐
2.2	Data on AM consumption should be collected directly in the case study farms through questionnaire interviews (in this case you can stop to fill in this questionnaire here);	☐
2.3	Comments:	

3 Type of database where the data on AM use in the case study farms are available:

3.1	Public database freely accessible	☐
3.2	Public database with restricted access;	☐
3.3	Private database;	☐
3.4	Other options (please specify):	☐
3.5	Comments:	

4 Database accessibility for the ROADMAP case study leader:

4.1	We have free access to the database;	☐
4.2	We should ask a permission to accede;	☐
4.3	A permission to accede has been already obtained;	☐
4.4	We have asked a permission to accede and we are waiting for an answer;	☐
4.5	We have not obtained the permission;	☐
4.6	We have only a limited access to data (please specify such limitations):	☐
4.7	Other options (please specify):	☐
4.8	Comments:	

5 Possibilities of data extraction from the accessible database:

5.1	We can directly extract data from the database by ourselves;	☐
5.2	The database manager extracts the data according to our requests;	☐
5.3	The database manager extracts the data after examination and eventually selection of our requests;	☐
5.4	We do not have this information yet;	☐
5.5	Other options (please specify):	☐
5.6	Comments:	

6 Level of aggregation of the accessible data:

6.1	We can obtain data from each single farm recorded in the database;	☐
6.2	We can only obtain aggregated data from the total farms recorded in the database;	☐
6.3	We do not have this information yet;	☐
6.4	We can obtain separated aggregations by several categories of farms (e.g. farm size, production system, use of antimicrobials, etc., please specify):	☐
6.5	Other options (please specify):	☐
6.6	Comments:	

7 Number of farms and animals recorded in the database:

		How may farms are recorded in the database?	It is possible to provide the number of animals present on each of the farms in the database?
7.1	Total farms recorded in the database:		Yes ☐; No ☐ ; I do not know ☐
7.2	- of which farrow-to-wean farms:		Yes ☐; No ☐ ; I do not know ☐

7.3 - of which wean-to-finish farms:		Yes ☐; No ☐ ; I do not know ☐
7.4 - of which finishing farms:		Yes ☐; No ☐ ; I do not know ☐
7.5 Comments:		

8 Product certifications in the farms recorded in the database (if you do not have this information, please indicate it in the comments):

8.1 Organic (EU regulation)	☐	Number of farms	
8.2 PDO/PGI (EU regulation)	☐	Number of farms	
8.3 Produced without antibiotics;	☐	Number of farms	
8.4 Improved animal welfare standards	☐	Number of farms	
8.5 GMO free	☐	Number of farms	
8.6 Improved environmental standards	☐	Number of farms	
8.7 Other (specify)	☐	Number of farms	
8.8 Other (specify)	☐	Number of farms	
8.9 Other (specify)	☐	Number of farms	
8.10 Comments:			

9 Information on the characteristics of the farmers and the holdings:

Is information about the following characteristics of the case study farmers and holdings available in the database?	
9.1 Sex of farm manager	Yes ☐; No ☐ ; I do not know ☐
9.2 Age of farm manager	Yes ☐; No ☐ ; I do not know ☐
9.3 Education level of farm manager	Yes ☐; No ☐ ; I do not know ☐
9.4 Type of farm business (family holding, company, etc.)	Yes ☐; No ☐; I do not know ☐
9.5 Age of pigsty buildings	Yes ☐; No ☐; I do not know ☐
Comments: 9.6	

10 Information on antimicrobial products and respective metrics available in the database:

Is information about the following aspects of AM products consumed in the case study farms and respective metrics available in the database?	
10.1 The database reports the AM use per active principle on each farm;	Yes ☐; No ☐; I do not know ☐
10.2 The database reports the use per AM class on each farm;	Yes ☐; No ☐; I do not know ☐
10.3 The AM use metrics is in mg on each farm;	Yes ☐; No ☐; I do not know ☐
10.4 The AM use metrics is in mg per PCU on each farm (population correction unit, i.e. kg of animal biomass);	Yes ☐; No ☐; I do not know ☐
10.5 The AM use metrics is in DDD (defined daily doses) on each farm;	Yes ☐; No ☐; I do not know ☐
10.6 The AM use metrics is in DCD (defined course doses) on each farm;	Yes ☐; No ☐; I do not know ☐
10.7 Other metrics (specify)	
10.8 Comments:	

11 Information on technical and economic data available in the database:

Is information about the following aspects available in the database?	
11.1 Data on consumption of technical means on each individual farm (e.g. weaner/grower pigs, feed, energy, fuels, water, straws and bedding, medicines, labour, etc.);	Yes ☐; No ☐; I do not know ☐
11.2 Data on technical indicators on each individual farm (e.g. number of pigs per batch; mortality; average weight in/out; average days of rearing/finishing herds; feed conversion ratios; average daily growth; weaning age; weaned pig per saw; etc.);	Yes ☐; No ☐; I do not know ☐
11.3 Data on costs for the use of technical means, professional services, and farm facilities on each individual farm;	Yes ☐; No ☐; I do not know ☐
11.4 Comments:	

12 Information on time series of data in the database:

12.1 Data are available starting from the year:	
12.2 Comments:	

THANK YOU FOR YOUR ANSWERS

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Annex 3 – Standard report outline on the information on national legislation and policies to be provided

ROADMAP - TASK 1.3

Prudent use of antimicrobials in livestock farming
Evolutionary analysis of the regulatory and institutional context

Information on national legislation and policies to be provided by case-study leaders

(Detailed outline for reporting)

Sections

The Roadmap Country Leaders will provide the T1.3 leader with the information concerning their own countries detailed under points from 1 to 5 below. **Deadline is the 15th of May 2020.**

1. National action plans and strategies for a more prudent use of AMs in veterinary medicine:

Provide the English version(s) of the document(s) that define the national strategy or action plan of your country or synthesis in English.

Provide also detailed information on the following aspects:

1.1. Areas covered:

1.1.1. Monitoring and surveillance of AMR and antimicrobial use in both humans and animals;

1.1.2. Risk management measures;

1.1.3. Risk communication strategies;

1.1.4. Guidelines for:

- prudent use;
- treatment and husbandry management;
- education and training;
- research;

1.2. Targets or indicators for monitoring and reporting the implementation progress and assessing the effectiveness of the measures undertaken;

1.3. Animal species targeted and respective priorities;

1.4. AM categories under specific targets;

1.5. National authorities involved in the strategy (responsible for food, agriculture, environment, human health and animal health);

1.6. Systems for registering and identifying herds and flocks to facilitate monitoring;

1.7. Targets for reducing AM use;

1.8. Measures restricting the prophylactic use of antimicrobials and minimising metaphylactic use;

1.9. Financial measures to promote the prudent AM use and the use of alternatives (e.g. differentiated taxes on sales and differentiated fees for granting marketing authorisations for certain medicines);

1.10. Measures for resolving potential conflicts of interest where parties are involved in AM prescription or supply;

1.11. Measures strengthening the position of the AM prescriber in relation to the farmer (e.g. registered contracts between farmers and veterinary practitioners which include regular visits by the veterinarian to the farm; guidelines including requirements to perform susceptibility testing);

1.12. Controls on the biosecurity standards in herds and flocks;

1.13. Treatment guidelines covering the choice of treatment and issuing of prescriptions by veterinarians, and the administration of antimicrobials to animals by farmers;

1.14. Maximum acceptable levels of AM use in herds and flocks, and action plans for reducing use where it is currently above the set limits;

1.15. AM usage limits and action plans for prescribing antimicrobials to non-food-producing animals;

1.16. Benchmarking systems to identify farms with high AM use and obligations for reduction;

1.17. Risk warning systems for veterinary practitioners prescribing AM high volumes, and farmers administering high levels of AMs to their animals;

1.18. Incentives to support animal health improvements on an ongoing basis, preventing diseases and ameliorating hygiene standards;

1.19. Animal health programmes based on good hygiene practices and other preventive measures, and discouraging routine prophylaxis;

1.20. Control measures preventing the spread of AM resistant bacteria;

1.21. Risk-based controls and other measures provided for by legislation, following guidance (e.g. codes of practice) on prudent AM use;

1.22. Methods for evaluating and assessing the effectiveness of the measures taken under the national strategy on AMR.

1.23. Total financial resources devoted to the national plan/strategy and specific actions;

1.24. Inclusion of specific measures related to the issue in the national Rural Development Policy;

1.25. Existence of regional plans, coordination with the national and the European level, monitoring and reporting on regional plan implementation;

2. Monitoring AM veterinary use and AM resistance in animal farms and along the food supply chain:

2.1. Documentation related to the monitoring on AM veterinary use has to be provided within the framework of the Task T1.2;

2.2. Provide an English version (or syntheses in English) of the national reports on monitoring AM resistance in animal farms and along the food supply chain issued in the last five years according to the Commission Implementing Decision 2013/652/EU of 12 November 2013;

2.3. Provide the available information and data on other indicators (than those related to points 2.1 and 2.2 above) testing the efficacy of the national strategy for a more prudent AM use in your country;

3. Implementation of the new European Legislation on veterinary medicinal products - Reg. (EU) 2019/6:

Provide detailed information on the current state of implementation in your country of the following provisions of the Reg. (EU) 2019/6 related to AMs, by specifying if and how the provisions have already been implemented, and if your country have provided on the same issues stricter rules and criteria than those indicated by the European regulation:

- Marketing authorizations (subject to taking into consideration potential development of AMR – art. 5, 8, 35, 36, 37);
    - Art. 5 - Validity of a marketing authorisation for a veterinary medicinal product for an unlimited time;
    - Art. 8 - Additional information for authorizations of AM veterinary medicinal products:
        - (a) documentation on the direct or indirect risks to public or animal health or the environment of use of the antimicrobial veterinary medicinal product in animals;

        - (b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of the veterinary medicinal product;
    - Art. 35 – The assessment report for the authorization should include special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to limit the risk of development of resistance;
    - Art. 36 - Post-authorisation studies for AM veterinary medicinal products requested by competent authorities to ensure that the benefit-risk balance remains positive given the potential development of AMR;
    - Art. 37 – Marketing authorization refusal in case that:
        - the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health;
        - the antimicrobial is reserved for treatment of certain infections in humans (subject to criteria and a specific list to be issued by Commissions).

- Art.34 - Classification of AM as veterinary medicinal products **subject to veterinary prescriptions**;

- Art. 57-59 - Collection of AMU data and responsibility of pharmaceutical sellers:
    - **data collection** on the volume of sales and the use per animal species and types of antimicrobial medicinal products:
        - data collection on the volume of sales and the use per types of antimicrobial medicinal products for poultry and pigs;
        - data collection on the volume of sales and the use per types of antimicrobial medicinal products for food-producing animals other than poultry and pigs;
        - data collection on the volume of sales and the use per types of antimicrobial medicinal products for all types of animals bred or kept;
    - **obligations of marketing authorisation holders**:
        - record the dates its authorised veterinary medicinal products are placed on the market;
        - record information on the availability for each veterinary medicinal product;
        - provide the competent authorities with all data in its possession relating to the volume of sales of the veterinary medicinal product concerned;
        - record in the product database the annual volume of sales for each of its veterinary medicinal products;

- Art. 105 - **Prescriptions of veterinary AM**:

- Prescriptions for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian;
- Justification for a veterinary prescription of antimicrobial medicinal products, in particular for metaphylaxis and prophylaxis;
- Issue of veterinary prescriptions only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.
- Exclusion of prescriptions of antimicrobial medicinal products by professionals other than veterinarians;
- Veterinary prescriptions shall contain any warnings necessary to ensure prudent use of antimicrobials, where relevant;
- Prescription of antimicrobial medicinal products for metaphylaxis or prophylaxis only for a limited duration to cover the period of risk;
- The validity of veterinary prescriptions for antimicrobial medicinal products for five days from the date of its issue;

- Art. 107 - **Use of veterinary AM**:
  - forbidden use by routine or to compensate for poor hygiene, inadequate animal husbandry or lack of care or poor farm management;
  - forbidden use as growth promotes or to increase yield;
  - forbidden use for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or an infectious disease is very high and the consequences are likely to be severe; limitation, in such cases, of the use of antibiotic medicinal products for prophylaxis to the administration to an individual animal only;
  - allowed use for metaphylaxis only when the risk of spread of an infection or an infectious disease in the group of animals is high and where no other appropriate alternatives are available;
    - provision of guidance by the competent authorities regarding such other appropriate alternatives and active support to the development;
    - application of guidelines which promote the understanding of risk factors associated with metaphylaxis and include criteria for its application;
  - forbidden derogated use outside the terms of the marketing authorisation for the antimicrobials reserved for treatment of certain infections in humans (Article 37(5));
  - establishment of lists of antimicrobials which shall not be used outside the terms of the marketing authorisation or shall only be used subject to certain conditions and further restrictions to the use of certain antimicrobials in relation with the implementation of a national policy on prudent AM use.

- Art. 119 – **Forbidden distribution** of AM veterinary medicinal products for promotional purposes as samples or in any other presentation.

4. Implementation of new European Legislation on medicated animal feeds - Reg. (EU) 2019/4

Provide detailed information on the current state of implementation in your country of the following provisions of the Reg. (EU) 2019/4 related to AMs in medicated animal feeds, by specifying if and how the provisions have already been implemented, and if your country have provided on the same issues stricter rules and criteria than those indicated by the European regulation:

- Art. 4 – Application to medicated feed and intermediate products of the provisions related to the collection of AMU data by the Member States and responsibilities of pharmaceutical sellers (art. 57-59, Reg. 2019/6);
- Art. 7 - Specific maximum levels of cross-contamination in the non-target feed from AM active substances used in medicated feed and related methods of analysis;
- Art. 11 – Forbidden distribution of medicated feed containing antimicrobial veterinary medicinal products for promotional purposes as samples or in any other presentation;
- Art. 16 – Prescription of medicated feed:
    - exclusion of prescriptions of medicated feed containing antimicrobial veterinary medicinal products by professionals other than veterinarians;
    - forbidden use for food-producing animals of medicated feed for more than one treatment under the same veterinary prescription;
    - duration of a treatment complying with the summary of product characteristics of the veterinary medicinal product incorporated in the feed and, if not specified, not exceeding one month, or two weeks in case of a medicated feed containing antibiotic veterinary medicinal products;
    - the validity of the prescription of medicated feed containing antimicrobial veterinary medicinal products for a maximum period of five days;
    - exclusion of veterinary prescriptions of medicated feed with more than one veterinary medicinal product containing antimicrobials;
- Art. 17 – Use of medicated feed:
    - use of medicated feed containing antimicrobial veterinary medicinal following Article 107 of Regulation (EU) 2019/6;
    - exclusion of the use of medicated feed containing antimicrobials for prophylaxis (except in extraordinary cases when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe (Article 107 (3) of Reg.n (EU) 2019/6);
- Annexe 3 – Label information that inappropriate disposal of medicated feed poses serious threats to the environment and may, where relevant, contribute to antimicrobial resistance;

- Annexe 4 – Application of a 10% tolerance when the composition of a medicated feed or an intermediate product deviates from the amount of an antimicrobial active substance indicated on the label;

5. Private standards

5.1. Briefly describe the functioning of the system framing, in your country, the independent certification protocols for label claims related to livestock products obtained without the use of antibiotics, by detailing the main actors involved and respective roles played in setting up the system: certification agencies, producers organizations and unions, control authorities, downstream industries and their associations, retailers, and any other group of stakeholders concerned.

5.2. For the livestock products listed below indicate the presence, in your country, of independent certification protocols for labels claiming that the product is obtained without the use of antibiotics during the whole production process or during a part of it.

For each type of product identify the existing certification protocols and for each protocol indicate the following:

- Identification code;
- Label claim;
- Application scope (e.g.: production without the use of antibiotics in breeding farm, traceability system in slaughterhouses and meat processing factories);
- Protocol key points;

5.2.1. Poultry eggs;

5.2.2. Poultry meat;

5.2.3. Pig meat;

5.2.4. Bovine meat;

5.2.5. Sheep meat;

5.2.6. Other meat;

5.2.7.Cow milk;

5.2.8.Non-cow milk;

5.2.9.Fish;

5.2.10. Other animal products.

6. Overview of the evolution of the national policies and legislation on AM use and control of AM resistance in livestock farming

Briefly describe the evolution of the political and legislative framework relating to the use of AMs in livestock farming and the control of AM resistance within your country, taking into consideration the following elements:

6.1. The situation before the European regulation n. 1831/2003 which banned the use of antibiotics as growth promoters on European Union farms from 2006;

6.2. The main developments after the 2006 ban, following increasing political pressures for tighter control on antibiotic use in European livestock farming;

6.3. The future developments given the entry into force, starting from January 2022, of the new regulations on veterinary drugs and medicated feed.

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