EPRUMA

European Platform for the Responsible Use of Medicines in Animals

EPRUMA best-practice framework for the use of antibiotics in food-producing animals

REACHING FOR THE NEXT LEVEL

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RATIONALE

Since its publication in 2008, the ´EPRUMA best-practice framework for the use of antibiotics in food-producing animals[1] has become a much referenced document, pointing out the effectiveness of a multi-stakeholder approach to promote Responsible Use of medicines in animals. Enhanced expertise and raised expectations prompt further development to contribute to new progress.

The current document builds on this foundation and should be considered in conjunction with the 2008 EPRUMA best-practice framework document. Organisations initiating promotional activities on the Responsible Use of medicines in animals should first familiarise themselves with the initial framework document and follow its guidance before embarking on activities to implement the current document.

Where the initial document provides a general approach to the issue and is limited to the Responsible Use of antibiotics, the current document combines a holistic and specific approach to facilitate the further optimisation of animal health at specific sector level and at individual farm level. Tailoring to the local situation of an individual farm and final implementation are the shared responsibility of the farm owner/animal caretaker (hereafter referred to as 'farmer') and other professional visitors to the farm, such as veterinarians, feed and husbandry experts, and biosecurity specialists. Efforts made by the farmer and these professional consultants, supported by all other stakeholders, will result in an optimal level of animal health and welfare. Consequently this facilitates and drives the Responsible Use of veterinary medicines, according to the adage *'As little as possible and as much as necessary'*.

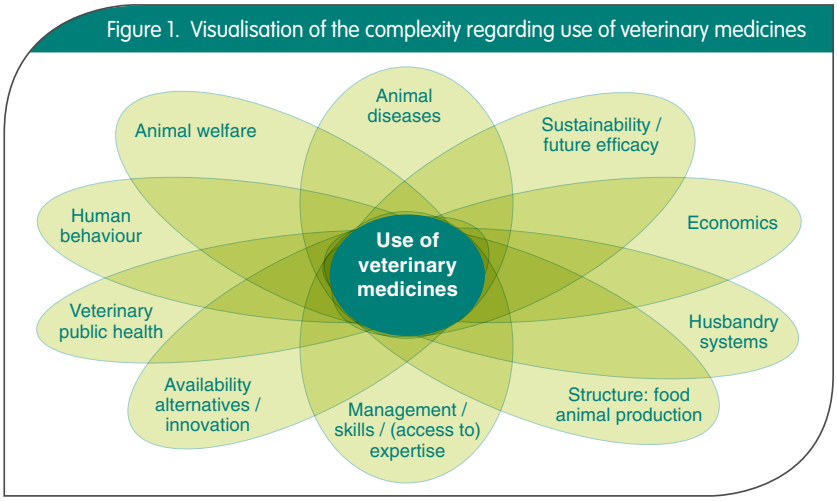
[1] The 2008 version of EPRUMA's best-practice framework document is available on www.epruma.eu/publications/brochures

SCOPE

This document outlines a 'next level' approach following on from the 2008 ´EPRUMA best-practice framework for the use of antibiotics in food-producing animals´. It presents both a more holistic and a more specific approach to implementing Responsible Use of antibiotics for further optimisation of animal health:

- Holistically, this document addresses the complexity of the Responsible Use of veterinary medicines and the interdependency with factors like animal health, veterinary public health, sustainability of food animal production, availability of veterinary medicines such as vaccines, and socio-economic factors.
  Figure 1 provides a visualisation of this complexity.
- Specifically, this document aims to provide elements for a sector and farm-specific implementation, which will facilitate the development and maintenance of farm health plans.

Figure 1. Visualisation of the complexity regarding use of veterinary medicines



The main objective of this combined approach is to reach the highest achievable level of animal health by determining, working towards and maintaining an optimal balance between different elements that may have an impact on animal health, e.g. nutrition, housing, etc.

Nevertheless, even with the highest level of animal husbandry animals can still get sick. In that instance the first responsibility of the farmer and veterinarian is to restore the animal's health as quickly and thoroughly as possible. Monitoring the health status of an animal and the correct use of veterinary medicines and diagnostic products will often be elementary in such a situation and complies with the Responsible Use of veterinary medicines approach.

Focusing on the use of medicines in food-animal production and aligning with EPRUMA's objectives, the aims of this document are to:

- raise awareness of the common goal of protecting animal health and welfare, and public health;
- ensure that veterinary medicines are used responsibly to optimise their effectiveness now and in the future in all species for relevant illnesses;
- provide guidance for all stakeholders involved on how to achieve these objectives, with a particular focus on farmers and their professional consultants.

ANIMAL HEALTH – Facing the complexity

The actual level of animal health is the result of managing a wide range of factors, which can be grouped as follows:

- **animal specifics**
- **husbandry system**
- **farm management**

Each of these factors need to be addressed separately and in relation to the others.

The interdependency of several factors adds to the complexity. It is the role of the farmer to determine and implement the optimal combination in the health plan of the farm. If needed, the farmer can seek support from professional consultants.

It is not feasible to propose a 'one size fits all' health plan, due to this complexity and the variation which can be observed within each group of factors. Rather, this document aims to provide a list of building blocks that the farmer, with the support of professional consultants if required, can use to develop and implement a farm-specific health plan. For some elements of a farm-specific health plan a protocol-driven approach can be developed. Annex 1 provides an example of such a protocol, e.g. a decision tree regarding Responsible Use of veterinary antibiotics.

Major elements that can be addressed in the health plan are outlined in the following chapters.

ANIMAL-SPECIFIC FACTORS IMPACTING ANIMAL HEALTH

SPECIES

It is generally accepted that each species has unique features and challenges that require a specific healthcare approach. Also within a species the differences in requirements can be substantial.
For example, the requirements for:

- a gestating sow differ from those of a weaned piglet
- a hen producing hatching eggs to hatch broilers differ from those of the broilers originating from these eggs
- a dairy cow differ from a bull serving a herd of beef cows on marginal pastures

As most farms are designed to house only one or just a few species and as it is often not feasible to switch quickly without major adaptations to other species types, this factor will not be elaborated further here.

GENETICS (BREED)

The genetics of the animals not only determine the level of production efficiency, but also their ability to respond to infections, stress, etc.

Robustness can be defined as the ability to cope with, and/or adapt to, changing conditions. In essence this is genetically determined. However, even when animals have a genetic ability to be robust, the expression of this positive trait will depend on management factors. Optimised housing conditions, nutrition and vaccination programmes all contribute to the actual level of robustness that can be achieved by the animals.

Breeds for free-range production require different traits than breeds for conventional production systems. The farmer should select the genetics best suited for the purpose and the conditions the animals are likely to face. Animal breeders need to include the important traits for different production systems into their selection and breeding programmes and need to provide adequate and accurate information, allowing farmers to make the right choices.

HUSBANDRY SYSTEMS

The variation in husbandry systems is substantial and often the result of local conditions, like type of soil and climate, and efficiency and/or market-drivers. This limits the choices a farmer can make. In general, husbandry systems can be grouped along the following axes:

- indoor only production versus free range/access to outdoor
- batch (all-in/all-out) versus a continuous production flow

Table 1 lists some examples.

Table 1. Examples of husbandry systems

Access to outdoor	Batch production	Combination	Continuous flow
Only outdoor (severe conditions excluded)	Free-range pig fatteners	Closed farm free-range pig production (sows & piglets continuous and fatteners in batch)	Extensive sheep or beef production on marginal grounds
In/outdoor combined	Free-range broiler or egg production	Conventional beef production (outdoor cow-calf phase combined with indoor finishing phase (prior to slaughter)	Conventional milk production
Only indoor	Conventional broiler or other poultry meat production, egg production in barns or aviaries, conventional veal production	Closed farm conventional pig production (sows & piglets continuous and fatteners in batch)	Zero-grazing milk production

Production flow

INDOOR PRODUCTION

Indoor production **allows the farmer to provide conditions for the animals that are less dependent on the outside climate and to better control biosecurity, e.g. reduce the likelihood that an external infection pressure actually leads to infection of the animals.**

- Temperature, humidity, air flow, lighting and other factors can be managed for the animals' comfort. This requires the farmer to have adequate knowledge of the comfort conditions for each of the specific groups of animals housed and to have and use the required equipment to measure, control and maintain these conditions.
  Providers of such farm equipment and corresponding control software should instruct farmers on the appropriate use and maintenance.
  Other professional consultants visiting the farm can alert the farmer to conditions deviating from the optimum and provide expertise on how to re-attain the optimum level.
- Biosecurity in an indoor housing system can offer four 'barriers' to infection, e.g.
  - Access to the farm is the first barrier. The risk that wildlife or other animals transfer infections to the farm animals can be adequately minimised. A quarantine period with a separated facility for new farm animals prior to final introduction to the group will reduce the risk of new animals infecting the group. Access should only be allowed to professionals that can contribute to the maintenance or, when necessary, the improvement of the health status of the animals or the management of the farm. Accurate registration of visitors will be an important resource for tracking and tracing arising or expected infections.

- The natural immune response represents the second barrier, which can protect each individual animal against infections. The natural immunity can be used to its full potential through an adequate vaccination programme and can be enhanced by proper nutrition, stress-free housing conditions, etc.
- If the animals are housed in groups, these groups can be separated, which then represents a third barrier. This will limit the likelihood of an infection spreading to all animals on the farm or reduce the speed of spread, resulting in an extra time-window for additional actions.
- Cleaning and disinfection is another major component of biosecurity, which allows for a significant reduction of the infection pressure originating from the animals that were previously housed in the building. Indoor production facilitates proper cleaning and disinfection if this aspect is considered during the design of the buildings (like for floors, walls, roofs and equipment). The farmer is responsible for the proper cleaning and disinfection which can only be achieved when no animals are housed in the building (barn, compartment) and after a sufficient drying time. The professional consultants, like biosecurity experts, can advise on proper protocols and evaluate the achieved efficacy.

- Confinement to an allotted space is the basic principle of indoor production. Group housing is preferred from an animal welfare perspective. However, there can be situations when temporary or structural individual housing might be preferred, such as separation of sick animals to prevent disease transmission, to allow for individual treatment, and adequate recovery time or to avoid undesired behaviour such as fighting between animals, mainly males. The space allocated to each individual animal, whether housed individually or in a group, should be sufficient to avoid welfare issues.

FREE RANGE OR OUTDOOR ACCESS

Free range or outdoor access is often preferred by a specific group of consumers or other stakeholders, due to real or perceived welfare benefits. For the farmer this may bring additional challenges regarding maintenance of the optimal animal health and biosecurity level, as well as additional opportunities to differentiate the production for specific market segments.

- During periods when temperature, humidity, air flow, lighting and other factors do not match the required comfort level the management will be more complicated. Where the climate is unsuitable for the species farmed, permanent outdoor production is not feasible. Indoor housing with access to outdoor allows the animals an option of choice. Another option is to provide structures into which the animals can retire during unfavourable conditions.
  This requires the farmer to have adequate knowledge of the comfort requirements for the animals. Providers of the structures mentioned should instruct farmers on the appropriate use and maintenance. The veterinarian and other professional consultants can alert the farmer on conditions deviating from the optimum and provide expert knowledge on how to re-attain the optimum levels.

- Achieving and maintaining an adequate level of biosecurity is a major challenge for outdoor systems:
  - The access barrier cannot be as effective as for indoor systems. Droppings or other secretions from overflying birds are a risk for infection which cannot be eliminated. Direct contact with these secretions as well as other wildlife and neighbouring farmed animals will depend on the type of fencing in place. During periods of high infection pressure, access to free-range systems can be denied for animal health or public health reasons.
  - This makes the efficacy of the barrier around each individual animal of eminent importance. An adequate vaccination programme, which should include vaccinations against infections potentially transferred via wildlife, will be elementary to achieve the full potential of this barrier. Proper nutrition and

stress-free housing conditions enhance the efficacy of vaccinations.

- Group housing is the common system in free-range. The ability of this third barrier to reduce the spread of an infection to other groups on the farm is limited similarly to the access barrier.
- Cleaning and disinfection is a major challenge for outdoor systems. Cleaning of the outdoor area is only feasible with limitations and disinfection is not possible at all. Elimination or even a significant reduction of pathogens cannot be expected, thereby representing a significant risk for the next group of animals. Nevertheless, the farmer is responsible for cleaning as well as possible. The equipment used and the structures for shelter during unfavourable conditions should be properly cleaned and disinfected, as their contact with the animals is intense. Biosecurity experts can advise on proper protocols and evaluate the achieved efficacy.

› As mentioned earlier, group housing is the common system in free range. However, there can be situations that require temporary or structural individual housing, like for sick animals to prevent disease transmission, to allow for individual treatment, rest and adequate recovery time or to avoid undesired behaviour such as fighting between animals, mainly males. The space allocated, to each individual animal, should be sufficient to avoid welfare issues.

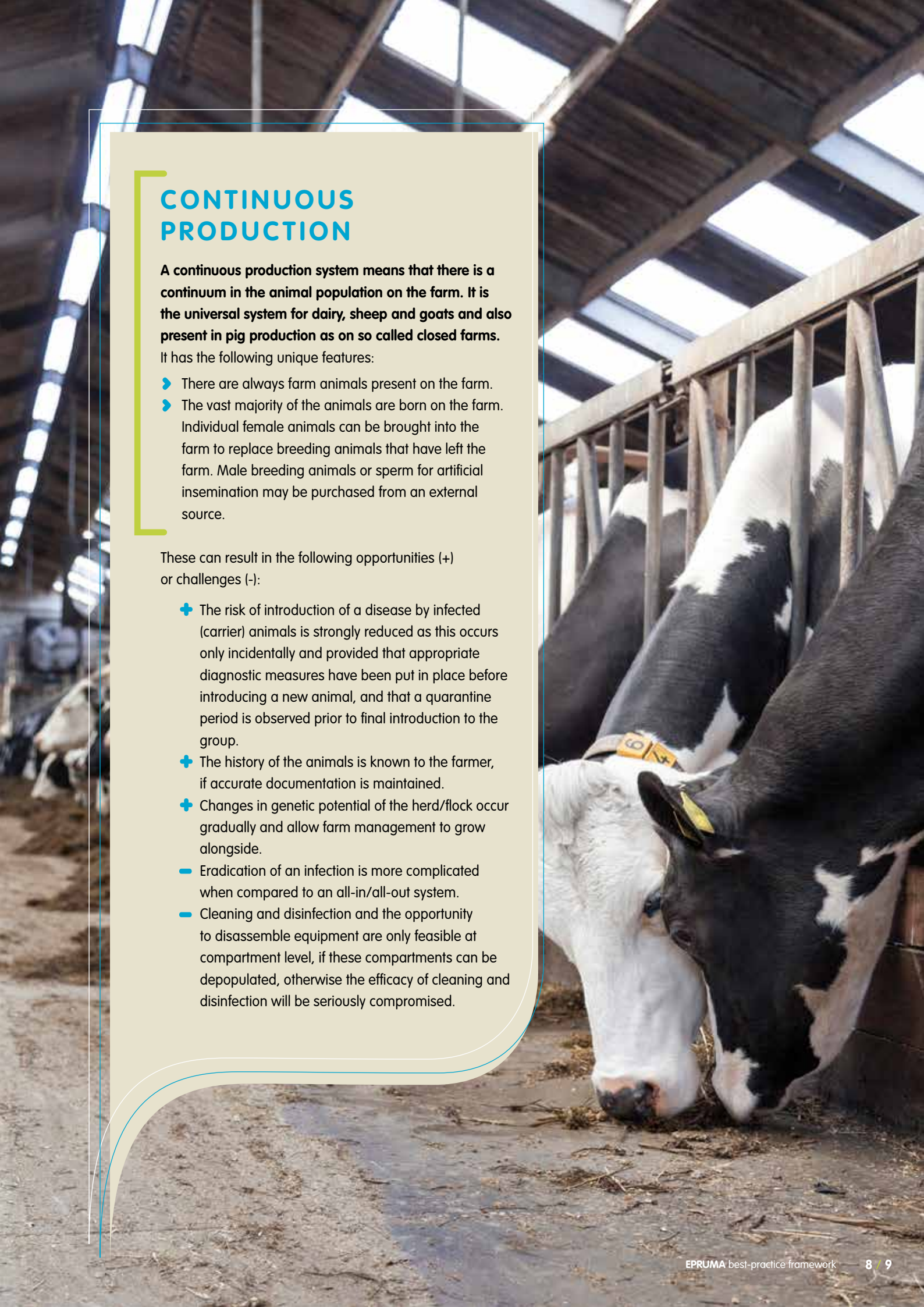
BATCH OR ALL-IN/ALL-OUT PRODUCTION

Batch or all-in/all-out production means that there is a period without any farm animals housed on the farm or without animals housed in a facility (barn, stable) separated from other facilities. This system, almost universal for poultry, common in pig and veal production but not used for dairy, sheep and goats, has some unique features:

› By definition a period without any farm animals housed (in a specific housing facility)
› For each batch new animals arrive on the farm, often with a similar genetic background and with a narrow variation in age, but they may have different origins and thereby vary in immune status
› Farm management is highly specialised.

These can result in the following opportunities (+) or challenges (-):

+ For the majority of diseases, during a period of absence of farmed animals, the infection pressure remaining from the previous group will quickly reduce, especially after proper cleaning, disinfection and drying is carried out. In this respect all-in/all-out can be considered an additional barrier, i.e. a hurdle between generations. It should be noted that other animals on the farm, like pets, may remain a reservoir for re-occurrence of an infection.
+ Cleaning and disinfection is more effective when combined with a period of absence of farmed animals (single-focus activity by farmer, disassembling equipment enhances efficacy of cleaning and disinfection, no risk of re-contamination, etc.).
– Lack of clear knowledge/data of origin and/or immune and health status of the animals for re-stocking complicates management. Knowledge and sharing of information regarding these parameters by the supplier will simplify the management.



CONTINUOUS PRODUCTION

A continuous production system means that there is a continuum in the animal population on the farm. It is the universal system for dairy, sheep and goats and also present in pig production as on so called closed farms.
It has the following unique features:

- There are always farm animals present on the farm.
- The vast majority of the animals are born on the farm. Individual female animals can be brought into the farm to replace breeding animals that have left the farm. Male breeding animals or sperm for artificial insemination may be purchased from an external source.

These can result in the following opportunities (+) or challenges (-):

- \+ The risk of introduction of a disease by infected (carrier) animals is strongly reduced as this occurs only incidentally and provided that appropriate diagnostic measures have been put in place before introducing a new animal, and that a quarantine period is observed prior to final introduction to the group.
- \+ The history of the animals is known to the farmer, if accurate documentation is maintained.
- \+ Changes in genetic potential of the herd/flock occur gradually and allow farm management to grow alongside.
- \- Eradication of an infection is more complicated when compared to an all-in/all-out system.
- \- Cleaning and disinfection and the opportunity to disassemble equipment are only feasible at compartment level, if these compartments can be depopulated, otherwise the efficacy of cleaning and disinfection will be seriously compromised.

MANAGEMENT

Management is defined here as all the activities of the farmer regarding the care of the animals. It has a material and non-material component. For the purpose of simplicity, management will be split into housing and equipment, biosecurity, nutrition (including drinking water), animal health aspects, like herd health plans (including vaccination programmes and veterinarian-farmer interaction), and how the farmer addresses each of these points, individually and combined.

HOUSING

Housing is intimately connected with the husbandry system. The housing provided to the animals should be adequate to accommodate their health and welfare needs during their entire stay on the farm.

Stocking densities, construction and furnishing should at least meet levels governed by national and international (EU) legislation.

Specific accommodation may be required for animals being introduced to the farm (a quarantine facility), especially if their history is unknown or their immune status differs from the animals already on the farm.
As animals may get sick, regardless of all the care provided, a 'sick bay' facility can be beneficial to treat sick animals to allow for an undisturbed recovery and to quarantine them during the period they might be infectious to other animals. For poultry such a facility is often not practical. For other species such a facility should be available per age group to avoid mixing of different age groups as this may result in additional spread of diseases due to variation in immune status.

BIOSECURITY

Biosecurity is also intimately connected with the husbandry system, as described before. The main objective for biosecurity is to protect the animals on the farms against any infections from elsewhere.

A significant part of the potential infections is spread by so called vectors. These range from wild animals, rodents and insects to domestic animals and human visitors, carrying the pathogens on their clothes or footwear. Some examples of such infections are: Classical Swine Fever carried by wild boars, Salmonella carried by rodents and Campylobacter carried by darkling beetles and flies. Prevention of infections spread by air is much more challenging and only avoidable following implementation of very sophisticated climate control systems.

Cleaning and disinfection, rodent control, group/herd specific clothing and footwear, registration of visitors, management of sick and fallen stock are elementary components of an adequate, farm-specific biosecurity plan. Depending on the husbandry system the available options need to be implemented in an optimal way.

NUTRITION

Nutrition, including drinking water, has an important impact on the animals' health. The amount and quality of water and feed provided and, in particular, their nutritional balance and composition should be adequate to meet the nutrition requirements corresponding to the species, sex and physiological stage.

That will allow the animal to maintain an adequate level of health and welfare, e.g. they should not be deficient in minerals, vitamins, proteins, energy, fibres, etc., bearing in mind that a good health status is a prerequisite for efficient livestock production. The feed should also be provided in a form that is adequate for optimal consumption, like meal, crumbs or small pellets for young animals and a courser structure for mature animals. Likewise, the particle size also has a direct effect on intestinal health.

The microbiological quality of the feed and drinking water, as delivered to the animals, is also of critical importance. It should be noted that their microbiological quality can deteriorate during storage on the farm and in feeding and drinking-water systems. Specific feed additives, like organic acids, may be used in feed or water under the conditions specified in their authorisations, to ensure that microbial quality of the feed or water is maintained. Additionally, specific products like acids, probiotics, prebiotics and metals like zinc and copper have been positively reviewed by the competent authorities for their positive effect on the intestinal microflora and, consequently, on animal health. However, it should be noted that it is also documented that some can (co-) select for antimicrobial resistance. In contrast to antibiotic veterinary medicines, these products (often authorised as feed additives) do not require a veterinary prescription before their use and may represent a risk for development and spread of resistance if used inappropriately.

ANIMAL HEALTH

Animal health aspects, like herd health plans, including vaccination programmes, and farmer interactions with veterinarians and other professional consultants, represent important and effective contributions.

- **Herd health plans need to be situation-specific to reach optimal efficacy.** They need to address the actual situation at each individual farm, its history, including suppliers and market, and the management style and skills of the farmer. This will require a regular update, at least each time after a major change occurs. The veterinarian and other professional consultants are excellent sources for expertise and advice to maintain an adequate and up-to-date herd health plan. Regarding vaccination programmes and the farmer interactions with veterinarians and other professional experts more specific principles apply.

- **Herd-specific vaccination programmes can very effectively contribute to a stable and high level of animal health if the following aspects are considered:**

  - The instructions on the product leaflet should be strictly followed in order to correctly apply the right vaccine, at the right dose, at the right time.

- Regular pre and post-vaccination monitoring to evaluate the efficacy and appropriateness of the selected vaccines.
- Vaccination of infected and/or sick animals should be avoided.
- Adequate knowledge of the cause/origin of diseases can point to specific circumstances, like E. coli infections following a respiratory infection. This can be controlled by an adequate vaccination programme against the primary, often viral infection. However, underlying factors, like climate control and introduction of new herd mates, need to be considered as well, for the vaccination to have optimal effect.
- Adequate knowledge of the epidemiology at a regional level allows the vaccination programme to be adapted before infection occurs on a specific farm.

› **The farmer's interaction with veterinarians and other professional consultants is the interface where all relevant animal health aspects need to be addressed.** For an optimal result it is necessary that these experts have an insight into the farm's specific conditions and history.

The veterinarian is the educated and experienced professional to be consulted by the farmer regarding specific animal health issues and the epidemiology of the region, and can also provide relevant advice regarding biosecurity. Other professional experts can be consulted regarding biosecurity, nutrition, housing/climate, etc., dependent, of course, on their specific expertise. Additionally, the veterinarian and these other experts can be adequate 'sounding boards' for the farmer to check the validity of his/her own ideas and opinions regarding the management and a safeguard against company blindness. Due to their knowledge of the situation on other farms, the professional consultants can also be excellent sources for proven best-practices from other farms, which might be applicable as well. An optimal veterinarian-farmer interaction can be achieved through regular farm visits by the veterinarian to discuss the farm specific situation in a transparent manner and with proper documentation of the outcome for future use. Further to the veterinarian's consultative role, he/she is the one who will examine, diagnose and prescribe the right treatment when necessary. The route of application of veterinary medicines to the animals shall be defined, taking into account a number of parameters. These should at least include the availability of the right equipment and procedures to control the risk of inappropriate use of the treatment and carry-over in case of in-feed or in-water administration. The decision tree ´Responsible Use of veterinary antibiotics' (Annex 1) provides guidance and includes the main elements that need to be included in this decision-making process. Continuous interaction between farmers and their veterinarians can ensure early detection of disease outbreaks and timely management of the case. Timely recognition of situations deviating from the optimal is a crucial component of Responsible Use of medicines in animals. If the disease symptoms are not manifest (yet) or only a number of the animals are affected, the veterinarian may be able to prescribe a less critical therapy (lower number of animals treated or chosen product) or use of medicines can even be avoided by changing a process, like temperature, nutrition, etc.

Additionally, adequate and transparent interaction between veterinarians and farmers is elementary to support pharmacovigilance, the system in which veterinarians and animal health service laboratories must report to the competent national authorities suspected adverse events, such as adverse reactions in animals or humans, suspected lack of expected efficacy, environmental problems, transmission of infections or insufficient withdrawal periods. The veterinarian's advice should be followed thoroughly, whenever

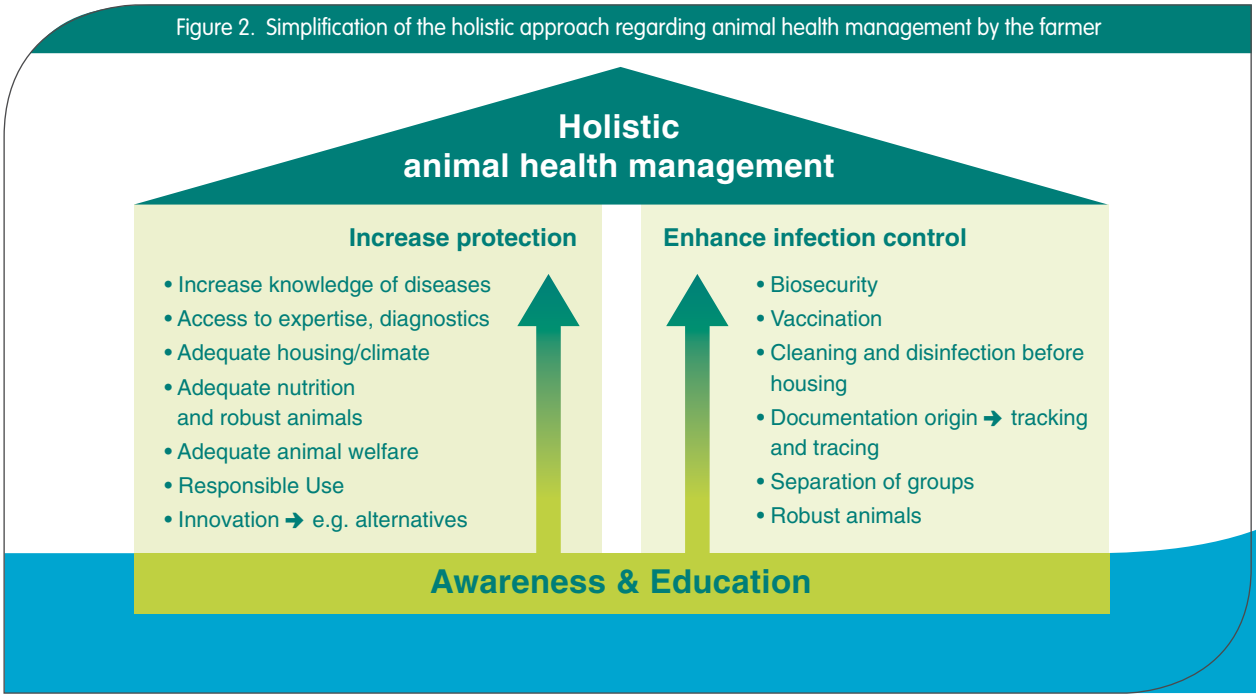
he/she calls for more diagnostic laboratory and/or sensitivity testing, and any deviations from the prescription dosage and instructions should be strictly avoided. Evaluation of the animal health status after the completion of the treatment can confirm its success.

- **The farmer's management is best described as the manner in which the farmer incorporates the elements as described earlier into the short, medium and long-term operation of the farm**. Each farm/farmer combination is unique. This can and will result in differences in short, medium and/or long-term decisions, e.g. the decisions for a specific farm may or may not be applicable to another, even if health management can be simplified by 'increasing protection and reducing the risk of infection'. The resources that a farmer can tap into are determined by the animal specific factors, available budget and the actual husbandry system as they are fixed or at least can only be marginally influenced or only adapted over a significant period.

The farmer's own knowledge and management skills result from their education, experiences gained over time and access to external advisors. Veterinarians are key advisors, however other professionals, like suppliers of feed, equipment and other farm supplies, and the buyers of farm produce can be additional sources of information and feedback and serve as 'sounding boards' for the farmer and a safeguard against complacency with the farm status quo.

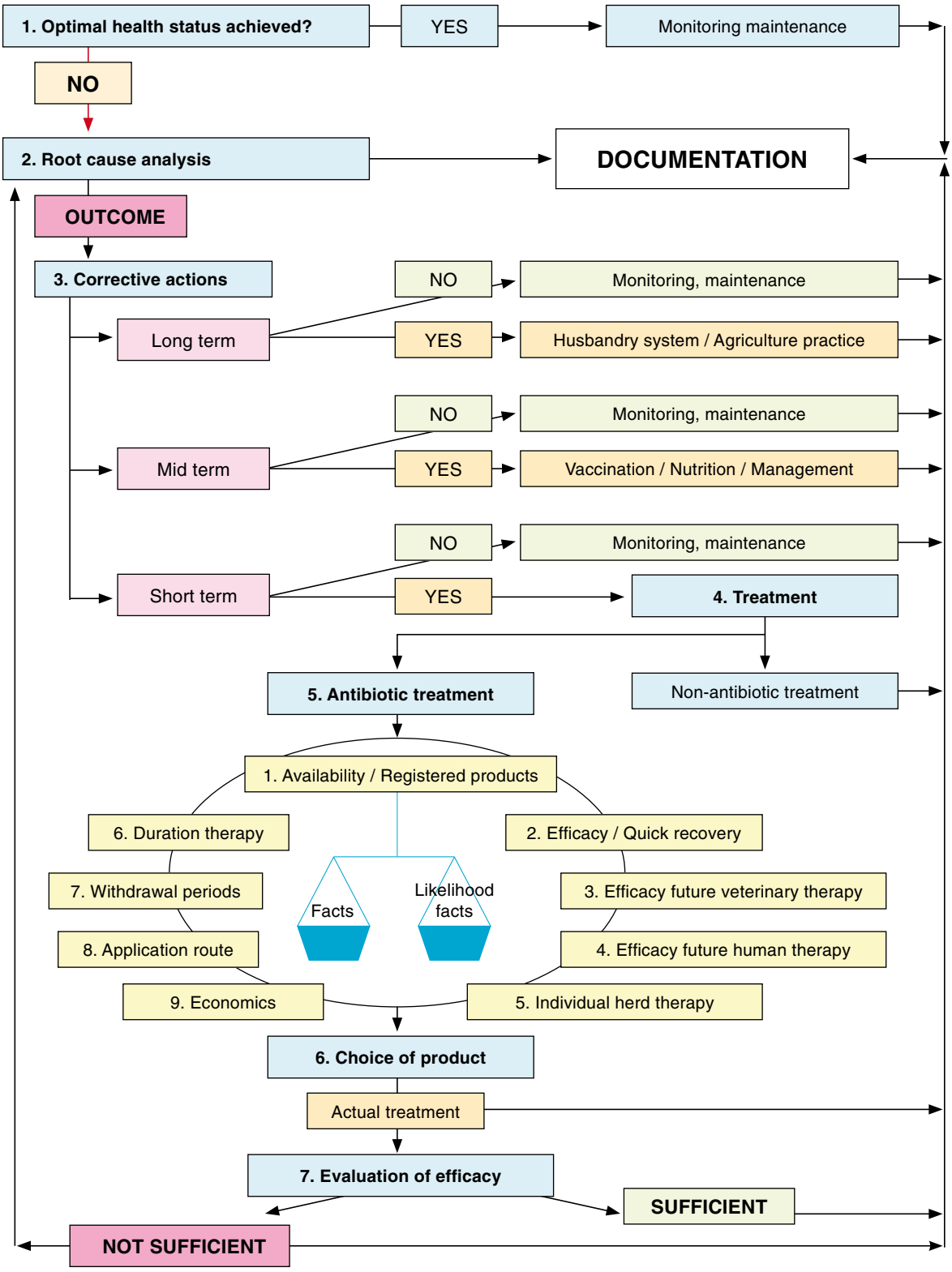
A multidisciplinary approach and interaction is recommended, but critical evaluation of the feedback is necessary. Finding the right set of decisions/balance for his/her specific farm is the biggest challenge that exists. This requires a holistic approach, which in a simplified way, is visualised in Figure 2.

Figure 2. Simplification of the holistic approach regarding animal health management by the farmer



ANNEX 1. DECISION TREE: Responsible Use of veterinary antibiotics

Decision tree: Responsible Use of veterinary antibiotics



EPRUMA partners

COPA/COGECA
European Farmers and Agri-Cooperatives

EGGVP
European Group for Generic Veterinary Products

EISA
European Initiative for Sustainable Development in Agriculture

EMVD
European Manufacturers of Veterinary Diagnostics

FECAVA
Federation of European Companion Animal Veterinary Associations

FEFAC
European Feed Manufacturers Federation

FESASS
European Federation for Animal Health and Sanitary Security

FVE
Federation of Veterinarians of Europe

IFAH-EUROPE
International Federation for Animal Health-Europe

PGEU
Pharmaceutical Group of the European Union

Associate partners

AMCRA
Centre for Expertise on Antibiotic Consumption and Resistance in Animals (Belgium)

RUMA
Responsible Use of Medicines in Agriculture Alliance (United Kingdom)

SDA
The Netherlands Veterinary Medicines Authority

VETRESPONSABLE
Platform for the Responsible Use of Medicines in Animals (Spain)

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