



Criteria and questionnaire for responsible use of antibiotics in food- producing animals

Version 2.0

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AXFOUNDATION

ANTONIA AX:SON JOHNSON FOUNDATION
FOR SUSTAINABLE DEVELOPMENT

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Introduction

Antibiotics¹ are one of our most important drugs, but an increased incidence of antibiotic resistance is a real threat to both human and animal health. To reverse the trend, increased responsibility needs to be taken in all sectors that use antibiotics. It is also necessary to have a broader, systems approach, a so-called 'One health approach', where connections between antibiotic use in the health sector and animal husbandry are considered. More than 70 percent of the antibiotics sold globally are used in the breeding of food-producing animals. Use in the animal sector is expected to increase by just over 60 percent by 2030 (compared with 2010). However, the proportion of antibiotics that goes to the animal sector varies greatly – in Sweden in 2019, it was about 13 percent². However, these figures are very uncertain due to difficulties in quantifying antibiotic use in animal husbandry in large parts of the world, and use in the aquaculture sector not having been properly mapped, or taken into account in global estimates.

Responsible antibiotic use and the 2030 Agenda for Sustainable Development

In 2015, global Heads of State and government adopted the United Nation's Agenda 2030, with its 17 global goals for sustainable development. The global goals must be achieved within a decade and balance the three dimensions of sustainable development: the economic, the social and the environmental. The implementation of the agenda is based on participation and participants from all sectors of society. Among other things, Agenda 2030 aims to eradicate poverty and hunger, and ensure that everyone can live a healthy life. Promoting responsible antibiotic use in animal husbandry thereby plays an important role in achieving many of the global goals.

Preventive animal welfare work to minimize the development and spread of antibiotic resistance

Animal husbandry in the EU shows great variation, besides tradition; site-specific conditions (such as climate, for example); breeding focus; which infectious diseases exist and which treatment strategies dominate, etc. Nevertheless, there are a number of general principles that are very important in order to achieve a reduced need for antibiotics in the breeding of food-producing animals. Actors in the food chain have a responsibility and an opportunity to contribute to minimizing the development and spread of antibiotic resistance in food-producing animals. In order to reduce the use of antibiotics in animal production, three levels of preventive work must be applied. Firstly, infections must be prevented from spreading between farms/facilities (external infection control). Secondly, the spread of infection between the animals within a farm/facility must be prevented, especially if an infection gets in or has taken place (internal infection control). Thirdly, the animals' conditions must be improved in order to manage infectious agents, i.e. the animals need to be robust, have a good welfare and a strong immune system.

In 2015, the European Commission requested what could be described as a scientific opinion from the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) on recommendations for reducing the need for antibiotics in animal husbandry. This resulted in a publication in 2017 ('RONAFA' opinion). RONAFA includes a document from the Federation of Veterinarians of Europe (FVE) where the organization has answered a number of questions regarding predominant infectious diseases,

¹ Antibiotics are defined in this document as natural and synthetic substances that in treatment have an inhibitory or killing effect on bacteria. Antiparasitic agents, disinfectants and antiseptics are not included in the definition.

² <https://sva.se/media/0hihej1c/swedres-svarm-2019.pdf>

the use of antibiotics, and possible measures to reduce the use of antibiotics. The material is available on EMA's website³. In 2019, the UN's Food and Agriculture Organization (FAO) produced a publication ('Prudent and efficient use of antimicrobials in pigs and poultry'⁴) which contains recommendations at a general level regarding the use of antibiotics, and also practical advice regarding good animal husbandry infection control, and management of bacterial infections for pigs and poultry. The publications from RONAFA and FAO constitute very good material that should be included in the in-depth discussions that take place with individual suppliers. Both the antibiotic criteria and the questions that supplement the antibiotic criteria (see below) have included aspects of these when it comes to cattle, pigs, poultry, and fish. RONAFA also presents a basis for sheep, goats, horses, rabbits, and bees.

Experience from Sweden, among others, shows that it is possible to reduce the need for antibiotics in animal husbandry completely. Animals with good welfare, including good health and good hygiene are the basis for a minimized need for antibiotics in animal husbandry. Through preventive animal health care, adequate animal environment, good care, suitable animal material and nutritionally adequate feed, the risk of disease outbreaks is reduced. Infection spread is minimized through infection control measures at the herd/facility and reduced animal trade. Healthy animals mean that the animals do not need to be treated with drugs and thereby, the risk of developing and spreading antibiotic-resistant bacteria is reduced. This is of benefit to both animal and public health, and contributes to the maintenance of animal production.

There is a clear link between good animal welfare and healthy animals, and these criteria, therefore, also extend to animal welfare. Consumers are increasingly prioritizing good animal welfare and food production with restricted antibiotic use. They expect retailers to ensure that the products on offer are produced with good animal welfare, and that food is safe. Good animal welfare generally results in healthier animals and healthy animals are a prerequisite for good animal welfare. Healthy animals do not need antibiotics. In order for an animal to have good welfare, the environment needs to be adapted to both the animal's physical and mental conditions. For some animal species, the young animals present the greatest risk group for disease outbreaks that require antibiotic treatment and, unfortunately, pneumonia and diarrhea are common, however, there is knowledge about how better animal husbandry and infection control could reduce the incidence and spread of disease. A dirty and crowded environment increases the risk and spread of disease, as well as parasites that reduce the animal's resilience. If the environment also happens to be barren, bleak and meaningless, it will not offer the animals any mental stimulation, or the opportunity for them to perform the most basic natural behaviors, i.e. behaviors that they have such a strong motivation to perform that, if they cannot perform them, it will lead to dissatisfaction, stress and frustration. An animal that has poor mental welfare is also at a greater risk of suffering from illness, as their immune system becomes weakened by prolonged stress. Behavioral problems due to poor welfare also risk contributing to further injuries in the entire group of animals. For example, animals can develop different types of cannibalism (tail biting in pigs and pecking in chickens) when kept in environments where they do not feel well and are stressed, resulting in an increased use of antibiotics.

³ <https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/advice-impacts-using-antimicrobials-animals/reducing-use-antimicrobial-agents-animal-husbandry>

⁴ <http://www.fao.org/documents/card/en/c/ca6729en/>

Antibiotics that are especially important for human health care

Certain antibiotics used in veterinary medicine are considered by the EMA to be particularly important for human health care, and because of this, caution should be exercised with regards to veterinary use. There are three groups of antibiotics, for which the authority considers that restrictions should apply to use: fluoroquinolones, third- and fourth-generation cephalosporins, and colistin. For this reason, these are also regulated in the criteria.

These criteria do not apply to residues of medicinal products in food

The antibiotic criteria in this document aim to encourage responsible use of antibiotics in animal husbandry to reduce the risk of developing antibiotic resistance. It is important to distinguish this issue from that of residues of medicines in food. There is a special regulatory framework within the EU that ensures that consumers are not exposed to risks in the form of drug residues in food. For medicinal products authorized for use in food-producing animals within the EU, there must be a decision on the MRL (maximum residue limit) which sets the limit value for medicinal products in food. If such a decision does not exist, the medicine must not be given to food-producing animals. Based on the MRL, a withdrawal period is also established for the medicinal product in question, i.e. the period of time that must elapse between the last day of treatment and the slaughter or delivery of milk, eggs or honey.

Other uses of antibiotics not included in these criteria

There is also some use of antibiotics in plant cultivation, mainly fruit cultivation, in some parts of the world. The antibiotics in question are mainly streptomycin, but oxytetracycline, quinolones and gentamicin are also used, with a purpose of protecting trees from bacterial diseases. This use is marginal when compared to the use in the animal sector, but it means that antibiotics are applied directly in the external environment. The use of antibiotics in plant cultivation is outside the scope of these criteria.

Criteria for responsible use of antibiotics in food-producing animals

For each criterion, there are associated questions to use for supplier dialogue and follow-ups (see appendix).

Criteria for reduced, direct antibiotic user

1. Antibiotics must not be used for growth promotion purposes.
2. Antibiotics must only be used following the prescription by the veterinarian and must be approved for use in food-producing animals in accordance with Codex⁵.
3. There must be detailed documentation of all the use of antibiotics, including via feed and water. The responsible veterinarian⁶ must regularly review and sign the documentation. Data on the use of antibiotics should be available on request from the actors in the supply chain.
4. If recurrent antibiotics are used for all, or the majority of, an age-specific category of animals, the reasons for this must be documented, an investigation must be carried out by a veterinarian and an action program to counteract the health problems must be developed and applied. The goal is to phase out recurring use.
5. Colistin, fluoroquinolones and third- or fourth-generation cephalosporins - antibiotics that are particularly important for human care, must only be used when a veterinarian deems that no other treatment options are effective.

Criteria for preventive, indirect interventions that can lead to reduced antibiotic use

6. For active work with reduced antibiotic use in the herd/facility, a plan with routines for preventive health care and reduced spread of infection must exist and be followed. The plan shall focus on strategic preventive animal health management, including infection control and animal welfare, and must include at least:
 - Need for quarantine, vaccinations, and other measures for good health.
 - Routines for infection control for visitors and for import and export of animals to/from the herd/facility.
 - Routines that minimize the spread of infection when introducing new animals and animal groups.
 - Routines for animal flows and infection control within the herd/facility.
 - Routines for cleaning and disinfecting the facility.
 - Routines for dealing with recurring health problems in different age groups.
 - Routines to actively reduce the need for antibiotics among young individuals by reducing stress.
 - Routines for regularly, periodically or annually, analyzing the facility's use of antibiotics and updating the health plan based on these results.
7. Animals must not be mutilated because of inadequate animal husbandry.
8. Animals must be kept in a way that gives them space to move freely and be able to rest in a way that is suitable for them.

⁵ Codex = Code of Practice to minimize and contain antimicrobial resistance, CAC/RCP 61-2005. Under certain circumstances, e.g. for certain food fish farming, instead of a veterinarian, a suitably trained person authorized in accordance with national law may be applicable (see Codex).

⁶ Under certain circumstances, e.g. for certain food fish farming, instead of a veterinarian, a suitably trained person authorized in accordance with national law may be applicable (see Codex).

Appendix: Questionnaire for follow-up on responsible use of antibiotics in food-producing animals

| Version control of appendix | | |
|-----------------------------|----------|--|
| V.2.0 | 09/06/20 | Version 2.0 developed in its entirety in connection with a new version of the criteria |
| V.2.01 | 09/12/20 | Minor revision of section 8 regarding cattle |
| V.2.02 | 01/20/21 | Addition: Comparison between criteria 1 to 8 and public regulation |
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The questions below are based on knowledge in the field and are linked to the antibiotic criteria version 2.0. The purpose is for these issues to function as a tool for follow-ups and dialogue with suppliers on the issue of antibiotics and related areas.

1. Antibiotics must not be used for growth promotion purposes.

- Are antibiotics used for growth promotion purposes (Antibiotic Growth Promoters (AGP) prohibited by law, private regulations or other applicable guidelines or policy document?)
- Does the supplier/producer waive AGP in the current production?
- Who gives advice on how and for which animal groups AGP is used?
- Is there documentation of such advice?
- Note: Coccidiostatics, which according to the EU definition are a feed additive, are not covered by the ban in these criteria for prevention and / or group treatment of animals.
- Verification: Extract from legislation, certifying that antibiotics are not used in pure growth promotion purpose; medical records/advisory documents signed by a veterinarian.

2. Antibiotics must only be used on prescription by a veterinarian and must be approved for use in food-producing animals in accordance with the Codex.

- Are all antibiotics for food-producing animals' prescription-only in accordance with legislation, private regulations or other applicable guidelines and policy documents?
- Is the veterinarian always involved in the diagnosis and choice of treatment?
- Does the production have a contract with a veterinarian for treatment and advice?
- Is there documentation that proves this (journals)?
- Are the antibiotics used listed in Table 1 of Regulation (EU) 37/2010?
- Verification: Records signed by a veterinarian.

3. There must be detailed documentation on all use of antibiotics, including via feed and water. The responsible veterinarian must regularly review and sign the documentation. Data on the use of antibiotics should be available on request from the actors in the supply chain⁷.

- Is there documentation that proves this (journals)?
- Has the responsible veterinarian signed the records?
- Does the documentation include how antibiotics are given (e.g. injection, in feed, in water)?
- How long is the documentation saved?
- Is there data on the use of antibiotics at an earlier stage in the supply chain for the animal/group of animals?
- Verification: Records signed by a veterinarian; medical records or other documentation from previous stage in the supply chain; routine for archiving records.

⁷The UK has the majority of grocery trade access to data on antibiotic use through the supply chain, and some also publish that type of data. Read more: <http://www.saveourantibiotics.org/media/1826/supermarket-antibiotics-policies-assessment-2020-report.pdf>. Red Tractor, the UK's leading quality certification for primary production, introduced 2018 requirements linked to antibiotic use and has developed a special form for reporting the farm's annual antibiotic consumption. Read more: <https://assurance.redtractor.org.uk/tools-and-library/templates> (Antibiotic Collation)

4. If recurrent antibiotics are used for all, or the majority of, an age-specific category of animals, the reasons for this must be documented, an investigation must be carried out by a veterinarian and an action program to counteract the health problems must be developed and applied. The goal is to phase out recurring use.

- Are antibiotics used regularly for all animals in a certain age category?
- Are there routines for identifying and investigating recurring health problems?
- Are developed action programs applied?
- Verification: Records signed by a veterinarian; routines for investigation of recurrent health problems; written action plans; documentation of implemented measures.

Below is a brief account of the dominant diseases leading to antibiotic use⁸. Note that the descriptions are general for EU animal husbandry and do not necessarily apply to all countries or producers. In Swedish animal husbandry, a large part of the criteria is met through legislation and guidelines from the industry.

Cattle

The cattle husbandry where most antibiotics are used is dairy cows and calf breeding. In dairy cows, mastitis (including during dry periods) is the disease that leads to the greatest use of antibiotics. Inflammation of the uterus, and hoof disorders also have some significance. In calf breeding, respiratory diseases and diseases leading to diarrhea are the most common. It is also in calf breeding, as well as for dry cows, that group treatment with antibiotics occurs. Mixing of young calves from different herds contributes to the spread of infection. As third and fourth generation cephalosporins usually do not have a milk withdrawal period, there is a risk that such antibiotics are overused in the dairy sector.

Pigs

In pig breeding, the diseases and the subsequent use of antibiotics are very dependent on the breeding stage the animal is in. In piglets, joint inflammation, neurological diseases, and diarrheal diseases predominate. During the weaning period, diarrhea predominates, but in cases where weaning pigs are transported to another farm for breeding, and then mixed with other pigs, respiratory diseases also occur. In slaughter pigs, various forms of diarrheal diseases and respiratory diseases are predominant. In sows, urogenital problems (e.g. Leptospirosis, a disease that is not common in Sweden) and pig fever predominate. Pigs can be treated individually with antibiotics, but group treatment is more common, either via water (which provides the possibility to limit the treatment to the boxes where disease occurs) or via feed (which usually means that the entire pigpen/section is given antibiotics).

⁸ This section is largely based on Chapter 1.7 of RONAFA:
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4666>

Poultry

All poultry are raised via hatcheries, which means transport of day-old chickens in all forms of poultry production. Routine group medication with antibiotics is not conducted in Sweden, but in other countries, antibiotic use is common in connection with this type of transport. The broilers have a relatively broad range of diseases: Jaundice inflammation (up to about 2 weeks of age), diarrheal diseases, respiratory diseases, and various types of arthritis. In laying hens, antibiotic use is usually low, as medication means waiting periods for the eggs. In turkeys, respiratory diseases and diarrheal diseases predominate. For poultry farming, group medication via water or feed is completely predominant.

Fish and other types of seafood

High diversity in aquaculture in terms of species, systems and farming conditions means the presence of a variety of diseases which can be caused by bacteria and which are treated with different types of antibiotics. For some species that are farmed extensively, however, e.g. mussels and oysters, no treatment is given even if the farm is affected by bacterial disease. Farming of fish and shellfish is, to a large extent, dependent on hatcheries for fry production, and although diseases are more common in later growth stages (so-called 'grow-out' phase), diseases also occur in hatcheries. In developing countries, the use of antibiotics for preventive purposes is common - especially in hatcheries but also at later development stages. In some cases, antibiotics are also used for diseases caused by viruses or parasites, something that is mainly driven by ignorance. Vaccines have been developed for a few species which can work well, more or less, depending on the disease. Deficiencies regarding water quality and farming conditions (oxygen, temperature, stocking density, etc.) result in stress and the emergence of diseases, but also lack of hygiene control at the plant, introduction of infection via water intake or via various organisms in connection with cultivation (e.g. birds) and infected larvae, can play a role. A variety of diseases are caused by bacteria and these are treated with antibiotics - e.g. vibriosis, aeromonosis, edwardsiellosis, pseudomonosis, flavobacteriosis, mycobacteriosis, streptococcosis, renibacteriosis..

5. Colistin, fluoroquinolones and third- or fourth-generation cephalosporins - antibiotics that are particularly important for human care, must only be used when a veterinarian deems that no other treatment options are effective.

- Is there a veterinary justification for it from an external source?
 - Autopsy report
 - Microbiological examination with determination of resistance
- Is there an occurrence of acute life-threatening conditions where it is not possible to wait for the response to the microbiological examination and the determination of resistance (even in such cases, microbiological examination with determination of resistance must be performed)?
- Verification: Records signed by a veterinarian.

6. For active work with reduced antibiotic use in the herd/facility, a plan with routines for preventive health care and reduced spread of infection must exist and be followed. The plan shall focus on strategic preventive animal health management, including infection control and animal welfare, and must include at least:

- Need for quarantine, vaccinations, and other measures for good health.
- Routines for infection control for visitors and for import and export of animals to/from the herd/facility.
- Routines that minimize the spread of infection when introducing new animals and animal groups.
- Routines for animal flows and infection control within the herd/facility.
- Routines for cleaning and disinfecting the facility.
- Routines for dealing with recurring health problems in different age groups.
- Routines to actively reduce the need for antibiotics among young individuals by reducing stress.
- Routines for regularly, periodically or annually, analyzing the facility's use of antibiotics and updating the health plan based on these results.
- Is there a health plan that meets the above criteria?
- Is there documentation that proves that the plan is followed?
- Verification: health plans with at least the above-mentioned points; medical records.

To support the follow-up of the plan with procedures for preventive measures, the following questions can be used:

All animals

- Are there conditions and routines that enable the animals to be kept in an environment that is good for them? In general, it should be ensured that:
 - The animals are kept in a climate that is adapted to them (cold or heat stress weakens the immune system).
 - Ventilation in the stalls is good and removes manure gases, moisture, infectious agents and dust (a humid confined environment increases the breeding ground for infectious agents and bad air increases the risk of respiratory diseases). For aquatic cultivation/farms - good water circulation reduces the accumulation of residues and increases oxygenation.
 - All-in/all-out systems are used (mainly applies to pigs, poultry, calves and shellfish), which means that the animal stalls are emptied between rounds so that they can be thoroughly cleaned and disinfected.
 - Animals from different groups and of different ages are not mixed (mainly applies to pigs, poultry and shellfish). If animals are mixed, there must be routines and conditions that reduce the risk of disease outbreaks and the spread of infection.
 - Water and feed are of good quality (these can otherwise be sources of infectious agents).
 - Group sizes and stocking densities are well thought out and prevent the infection from spreading to all animals on the farm.
 - The animals are moved as few times as possible during their lives.
- Are there routines to ensure that the animal receives anesthesia and pain relief during surgery? E.g. when castrating or dehorning.
- Are there routines and breeding goals that do not only focus on parameters related to the quantity and quality of meat and milk, but also on robust and healthy animals?
- Are relevant animal regulations complied with; such as the EU legislation and the OIE⁹ standards for animal welfare?

⁹ The World Organisation for Animal Health, previously the Office International des Epizooties (OIE).

Pigs

- Are there routines for responsible weaning? It is recommended that piglets are weaned after the age of 28 days as an earlier weaning can increase the incidence of disease, e.g. piglet diarrhea, and thus an increased use of antibiotics, and increases the risk of tail biting.
- Are there routines for responsible transport of piglets? An integrated production is recommended (i.e. where all animals stay on the same farm until slaughter), but if the piglets must be transported, this should take place, at the very earliest, after 28 days of age.
- Is there a routine to limit the number of farms that piglets come from? To limit the spread of infection, it is recommended that the piglets do not pass more than one growth stall and that the growth stalls receive piglets from as few farms as possible.
- Are there routines to minimize the transport time for piglets? It is recommended that the growth stall receive piglets from farms that are as close by as possible and that they have not been transported for more than eight hours.
- Does the growth stall work actively with good infection control throughout receiving stalls and sections to prevent disease outbreaks and the spread of infection? It is recommended that the growth stalls use rotation breeding with cleaning, disinfection, and idle time (i.e. all in - all out), that they have receiving stalls and work with sectioning.
- Do the pigs have straw or other material to root in, manipulate and explore in order to keep themselves occupied? Pigs are strongly motivated to explore and root, so this is important to be able to prevent, among other things, tail biting. Sows that will bear piglets need straw to be able to build nests.
- Are all pigs able to find space to eat at the same time if all the pigs are fed simultaneously? If all pigs are able to eat at the same time it reduces the risk of tail biting developing. If feeding stations or automatic feeding are used, care should be taken to ensure that these are present in such numbers that the pigs can calmly ingest their feed.
- Are there routines for castrating male pigs? Castration on pigs must be performed with prior anesthesia and pain relief. Other methods for avoiding surgical castration should be considered.
- Is a nose ring used on a pig? Pigs should not have a nose ring.

Cattle

- Are there routines to ensure that the calves receive colostrum to develop their immune system? Calves are dependent on colostrum to develop their immune system. Since calves in milk production are usually taken directly from their mother to produce milk for us consumers, it is important to ensure that the calf receives its colostrum.
- Is it ensured that the calves have free access to roughage after 2 weeks of age? For the first few weeks, the calf drinks only milk. It is recommended that the calves have free access to roughage after two weeks of age so that all stomachs, including the rumen, can start and function as they should. If the calves do not receive roughage, or receive too little, there is a high risk that they will develop stomach ulcers and other health conditions that require antibiotic treatment.
- Are there routines for responsible transport of calves, i.e. after four weeks of age, at the earliest? The calves should only be transported when they are no longer dependent on milk, which is after approximately four weeks of age.
- Is the transport of calves to their growing pens breeding stalls completed within a maximum time of eight hours? The breeding stalls should receive calves from farms as close by as possible, with a maximum transport time of eight hours.
- Are there routines in the breeding stalls to reduce the stress of transport and environmental change as well as possibilities of infection when calves from several farms gather in the same place (the 'kindergarten effect')? It is recommended that the breeding stalls receive calves from as few farms as possible. Integrated production (i.e. where all animals stay on the same farm until slaughter) can also be beneficial from an infection control point of view.
- Does the breeding stable work actively with good infection control through reception stalls and sections to prevent disease outbreaks and the spread of infection? It is recommended that the breeding stalls use rotation in breeding (all in - all out), that they have a receiving stall and work with sectioning.
- Are there routines to reduce the experience of pain during surgery on cattle? Dehorning of calves, castration of bull calves, removal of excess teats on heifer calves and nose ringing of bulls must be performed with prior anesthesia and pain relief. Methods for avoiding dehorning should be considered.

Sheep

- Are there routines to avoid sheep and lambs being transported for more than eight hours?
- Are there routines for reducing the experience of pain during surgical procedures in sheep? Dehorning on lambs or adult animals, as well as castration of ram lambs, must be performed with prior anesthesia and pain relief. In the first instance, other methods to avoid dehorning should be applied. Castration with a rubber ring should be avoided. Tail docking of lambs is done routinely in some countries but is something that needs to be phased out. If mutilation of any part of the tail occurs, it should be done with prior anesthesia and pain relief. Tail docking with rubber ring should be avoided. Mulesing must not be done. Mulesing is when the sheep's buttocks is shaved/scalped to prevent fly infestation in skin folds where dirt, urine and manure have accumulated.

Poultry

- Do the laying hens have litter to sandbathe in, raised perches and nests to lay their eggs in?
- Do the parents for laying hens and broilers have litter to sandbathe in and raised perches?
- How are the broilers kept? It is recommended that the stocking density is not too high. It is also very important that the broilers have a dry and clean litter bed, good ventilation, and adapted temperature to stay healthy.
- Is there active work with infection control in the flock? It is recommended that rotation breeding is used (all in - all out) with cleaning, disinfection, and idle time between rounds.

Fish and other types of seafood

- Are there routines to ensure good hygiene regarding care?
- Are there routines to ensure good quality of fry (disease-free)?
- How is good water quality ensured - regarding stocking density but also minimization of infection via water intake and via other animals in the vicinity of the facility (e.g. birds)?
- Does vaccination take place? If so, when and against which diseases?

7. Animals must not be mutilated because of inadequate animal husbandry

This criterion refers to procedures that can be avoided if the animal environment is good, such as tail docking and beak trimming. Procedures such as castration and dehorning are also to be classified as mutilations, but are usually not carried out primarily because the animal environment is deficient but because e.g. reduce aggression and harm to animals. However, all procedures must be performed with prior anesthesia and pain relief, regardless of the purpose for which they are performed.

- Are there routines for giving the pigs an environment that reduces/eliminates tail biting? Within the EU, it is forbidden to routinely dock the pigs' tails. When the tail is docked, the spinal canal is exposed, which leads to an increased risk of infections and boils, which are treated with antibiotics. There are many factors that affect the risk of tail biting, but among other things, the pigs should not be kept on fully-slatted floors, they should have enough space and straw, or other material to root in and to occupy themselves with. It is also recommended that all pigs are allowed to eat at the same time if all pigs are fed simultaneously. If there is automatic feeding, or if feeding stations are used, care should be taken to ensure that these are present in such numbers that the pigs can calmly ingest their feed.
- Are there routines to prevent the birds from pecking each other? Poultry should be allowed to have their beak intact (no beak trimming should take place) and instead, the birds should be offered a sufficiently good environment to prevent pecking behavior. This is mostly relevant for laying hens.
- Does mulesing occur in sheep? This should not occur.
- Are there action plans to be able to phase out tail docking of lambs?

8. Animals must be kept in a way that gives them space to move freely and be able to rest in a way that is suitable for them.

All animals

- Are the animals able to move as it is natural for their species; such as being able to turn and stretch throughout their body length? Systems that involve crating or caging of animals must be avoided. Terrestrial animals must be able to lie on a flat and dry surface that does not result in any injury. They must also have access to water

Pigs

- Are pregnant or lactating sows kept loose? Farrowing sows must be kept loose with access to litter to enable nest-building. Lactating sows must also be kept loose. Crating sows in connection with farrowing increases e.g. the risk of pig fever against which, antibiotics are given. A common argument for crating lactating sows is that they otherwise crush their piglets to death. This argument is only true if the pigs' pen is poorly designed. No sow voluntarily kills her young, but there is a risk of crushing, e.g. if the pens are too small, if there is no room for the piglets to escape when the sow lies down, if the piglet corner is poorly designed (too cold and lacks a roof) which means that the piglets lie down on/by the sow instead, or if the piglets are weak due to starvation or disease, which means that they do not have the strength to move quickly. Routinely, crating sows is thus a way of dealing with poor animal husbandry and there are other measures that are better for both animal health and welfare.
- Are the pigs kept on floors that are entirely solid, or at least solid in some places? The floor surface should not comprise of fully slatted surfaces but all or parts of the surface should consist of a solid floor with straw or other material that increases lying comfort.

Cattle

- Are cattle kept loose? Cattle must be kept loose. If dairy cows are kept tethered, there should be a plan for phasing out this system and, it is recommended that both loose and tethered animals are rested outdoors a few times a week and released on summer pasture.
- Are cattle kept with others? Cattle are distinct herd animals and should be kept together with their fellow species. After eight weeks of age, healthy calves are kept together in group pens.

Sheep

- Are sheep kept loose and kept together with other sheep? Sheep, including lambs, must be kept loose, and kept with their species because they are herd animals.

Poultry

- Are laying hens kept in free-range systems? They should be kept in free-range systems and not in cages. Cages without sand baths, nests and perches are banned in the EU.
- Are the litter beds kept dry and clean?

Comparison between criteria 1 to 8 and public regulation

Introduction

Antibiotic criteria 1 to 6 are largely aligned with Swedish legislation and, to some extent, with EU legislation. Criteria 7-8 are largely aligned with Swedish legislation and so some extent, but less, aligned with EU legislation. When Regulation (EU) 2019/6 on veterinary medicinal products takes effect 28 January 2022, compliance with EU legislation will increase for criteria 1-6. For a good overview of the new EU legislation, information from the [Medical Products Agency](#) is recommended (in Swedish).

Globally, there is no harmonized regulation for the use of antibiotics in animals kept for farming purposes. The Codex Alimentarius Commission, or Codex, is a program of food safety standards established by the FAO and the WHO. Codex has developed a guideline, Code of Practice to Minimize and Contain Antimicrobial Resistance, CAC/RCP 61-2005, which has served as a guide in the development of the antibiotic criteria. The Codex rules are not mandatory but should act as a benchmark in the event of a trade dispute in the World Trade Organization, WTO.

When it comes to animal welfare, there is no global regulation. Within the EU, there are animal welfare directives for protection of animals kept for farming purposes (98/58/EG), pigs (2008/120/EG), calves (2008/119/EG), laying hens (1999/74/EG) and broilers (2007/43/EG). However, in many cases, the requirements in these directives are insufficient for meeting the animal welfare aspects of the criteria.

Every year, the European Medicines Agency (EMA), publishes a [report](#) on the use of antibiotics in animals within the EU and the EEA. While it is, to a large extent, aggregated country data that is reported, the EMA report can provide guidance on which countries can be considered a higher risk when it comes to how antibiotics are used. Globally, the World Organization for Animal Health, OIE, has taken the initiative to develop a [global database](#), with annual reports.

The global animal protection organization, World Animal Protection, has produced the [Animal Protection Index](#), last updated in 2020. The index currently covers 50 countries spread across the world and it is possible to separate out the index which applies to keeping farm animals. It is also here that a rough guide can be given when it comes to risk assessment of individual countries.

Comparison between public regulation and criteria for reduced, direct antibiotic use

1. Antibiotics must not be used for growth promotion purposes.

- Codex: Paragraph 8, point 5.
- EU: Not allowed. Please note that Regulation (EU) 2019/6, which takes effect 28 January 2022, Article 118 requires that animal products imported into the Union come from animals that have not been given antibiotics for growth-promoting purposes.
- Sweden: See EU.

2. Antibiotics must only be used following the prescription by the veterinarian and must be approved for use in food-producing animals in accordance with Codex¹⁰.

- Codex: Paragraph 13 and Paragraph 59, point 3, including Paragraph 14.
- EU:
 - Up to and including 27 January 2022: Directive 2001/82/EG, Articles 66-67, including Chapter 3.
 - From 28 January 2022: Regulation (EU) 2019/6, Article 105, including Article 5.
- Sweden: See EU.

3. There must be detailed documentation of all the use of antibiotics, including via feed and water. The responsible veterinarian¹¹ must regularly review and sign the documentation. Data on the use of antibiotics should be available on request from the actors in the supply chain.

- Codex: Paragraph 59, point 11, including Paragraph 56. However, there is no requirement for signing.
- EU:
 - Up to and including 27 January 2022: Directive 2001/82/EG, Article 69, sets out basic requirements, member states may decide on additional requirements. No requirement for signing.
 - From 28 January 2022: Regulation (EU) 2019/6, Article 108, member states may decide on additional requirements. No requirement for signing.
- Sweden: See EU, for conditional drug use there are requirements for more detailed documentation, control by a veterinarian and signing of an animal welfare declaration, see SJVFS 2019:32, Chapter 4.

¹⁰ Codex = Code of Practice to minimize and contain antimicrobial resistance, CAC/RCP 61-2005. Under certain circumstances, e.g. for certain food fish farming, instead of a veterinarian, a suitably trained person authorized in accordance with national law may be applicable (see Codex).

¹¹ Under certain circumstances, e.g. for certain food fish farming, instead of a veterinarian, a suitably trained person authorized in accordance with national law may be applicable (see Codex).

4. If recurrent antibiotics are used for all, or the majority of, an age-specific category of animals, the reasons for this must be documented, an investigation must be carried out by a veterinarian and an action program to counteract the health problems must be developed and applied. The goal is to phase out recurring use.

- Codex: Paragraph 47 and Paragraph 59.
- EU:
 - Up to and including 27 January, 2022: No requirement.
 - From 28 January 2022: Regulation (EU) 2019/6, Article 107.
- Sweden. See EU, for conditional drug use, there are also requirements for herd investigation on site in the animal keeper's herd with special focus on disease incidence and animal health, see SJVFS 2019:32, Chapter 4.

5. Colistin, fluoroquinolones and third- or fourth-generation cephalosporins - antibiotics that are particularly important for human care, must only be used when a veterinarian deems that no other treatment options are effective.

- Codex: No requirement.
- EU:
 - Up to and including 27 January, 2022: No requirement.
 - From 28 January 2022: Regulation (EU) 2019/6 does not currently contain such requirements. However, Article 107 allows the Commission to establish a list of antibiotics that may not be used.
 - Sweden: Fluoroquinolones and third- or fourth-generation cephalosporins: Regulated by SJVFS 2019:32, Chapter 2, Paragraph 11.

Comparison between public regulation and criteria for preventive, indirect interventions that can lead to reduced antibiotic use

6. For active work with reduced antibiotic use in the herd/facility, a plan with routines for preventive health care and reduced spread of infection must exist and be followed. The plan shall focus on strategic preventive animal health management, including infection control and animal welfare (see page 6 regarding what the plan must include).

- Codex: Paragraph 59.
- EU:
 - Up to and including 27 January, 2022: No requirement.
 - From 28 January 2022: Regulation (EU) 2019/6 does not contain strict requirements regarding health plans, but Article 107 aims at responsible antibiotic use, and active work for preventive animal health care is an important part of this.
- Sweden. In the case of conditional drug use, there is a requirement for a herd investigation on site in the animal keeper's herd with special focus on disease incidence and animal health, see SJVFS 2019:32, Chapter 4. For herds connected to voluntary health control (see SJVFS 2015:17) the requirement is largely met.

7. Animals must not be mutilated because of inadequate animal husbandry.

- Outside the EU: There is normally no requirement for anesthesia during procedures such as castration, dehorning and tail docking. Beak trimming occurs mainly when keeping laying hens.
- Within the EU:
 - There is no requirement for anesthesia during procedures such as castration and dehorning in the EU regulation. National legislation exists in some countries.
 - The EU's Pig Directive 2008/120/EG contains a ban on tail docking, but there is the possibility of exceptions which are used systematically in most EU countries, where tail docking is carried out routinely and without anesthesia (in Finland and Lithuania, however, as in Sweden, there is no tail docking).
 - Tail docking is performed routinely on certain breeds of sheep and without anesthesia.
 - Beak trimming occurs mainly when keeping laying hens.
- Sweden: There is a requirement for anesthesia for all surgical procedures, including dehorning and castration, with the exception of castration of reindeer. Tail docking may only be performed if it is veterinarily justified and must then be performed with anesthesia. Beak trimming of chickens is prohibited.

8. Animals must be kept in a way that gives them space to move freely and be able to rest in a way that is suitable for them.

- Outside the EU: Tethering of dairy cows occurs. Animal husbandry of fattening calves and young cattle in ways that do not meet this requirement occurs. Fixed sows and litter-free systems are common in pig breeding. Litter-free stable systems can occur in sheep farming. Traditional cage keeping of laying hens (battery cages) occurs.
- Within the EU: Tethering of dairy cows occurs. Animal husbandry of fattening calves and young cattle in ways that do not meet the requirement occurs. Fixed sows and litter-free systems are common in pig breeding. Litter-free stable systems can occur in sheep farming. Traditional cage keeping of laying hens (battery cages) is prohibited, however, so-called decorated cages are allowed in most countries.
- Sweden: Tethering of dairy cows occurs, including rearing of young cattle in litter-free systems (slatted boxes) occurs. Furnished cages for chickens are allowed.



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