



VETERINARY
MEDICINES
AND
FOOD SAFETY

Healthy animals = safe food



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1. INTRODUCTION

Consumer well-being is essential

The well-being of consumers is essential to the development, licensing and use of veterinary medicines. The link is an obvious one: to have safe and healthy food of animal origin you must have safe and healthy animals. However, animals do get sick at times, so it is equally important to have safe veterinary medicines to treat and control disease and illness in animals, and ultimately to safeguard consumer health.

Healthy animals help to ensure a safe and sustainable food supply for a growing world population, and produce good quality food, such as meat, eggs and dairy products at affordable prices for consumers.

Therefore, veterinary medicines protect an animal's health, support its welfare and act as a guarantee to food safety. They contribute to public health by helping to prevent and control diseases in animals, e.g. zoonoses¹. This is true for both food-producing animals and pets. This booklet explains specific conditions that apply only to medicines for food-producing animals.

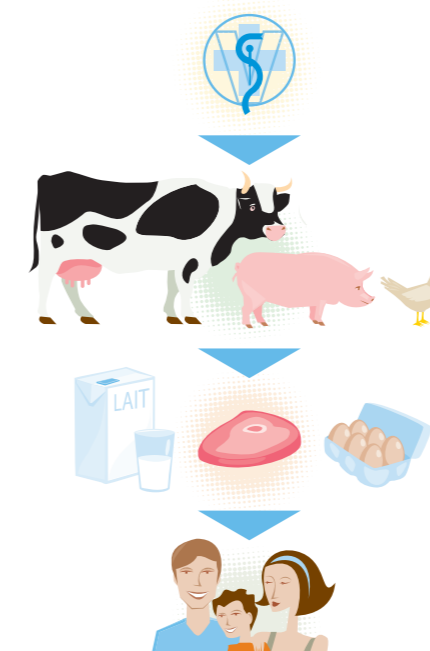
¹Zoonoses are animal diseases which are transmittable to people, e.g. rabies, ringworm, brucellosis and salmonellosis.

Use of veterinary medicines is strictly regulated

Farmers and veterinarians play a crucial role in ensuring a controlled use of veterinary medicines. For example, they keep records each time a food-producing animal is treated with a medicine. Furthermore, they follow strict rules and processes before the animal or its produce enters the food chain.

The public authorities, the veterinary profession and the farming community work together in order to guarantee that food from animals is free of disease and safe to eat. Health schemes, which include good preventive measures - such as vaccination - and veterinary medicines, are a key element to deliver safe food.

Before they can be authorised for use in animals, veterinary medicines must undergo exhaustive testing and are subjected to rigorous, independent scrutiny by scientists and regulators.



AS PART OF THAT PROCESS, REGULATORS AROUND THE WORLD SET STRICT LIMITS ON LEVELS AT WHICH TRACES OF MEDICINES IN MEAT, MILK, EGGS, AND OTHER FOODS DERIVED FROM ANIMALS ARE HARMLESS AND HAVE NO IMPACT ON THE CONSUMER'S HEALTH. THESE ARE KNOWN AS MAXIMUM RESIDUE LIMITS, OR MRLS, AND ARE LEGAL THRESHOLDS THAT MUST BE RESPECTED.

Establishing an MRL involves several steps. At each stage, regulators build in a safety factor designed to minimise any potential risk to those consuming food from treated animals. Withdrawal periods - the minimum time lapse required between the treatment of an animal and when it or its produce is allowed to enter the food chain - are also established for each veterinary medicine to ensure that if residues arise from treating animals, they are at levels below the MRL. This assures that no unsafe residues are found in food. This precautionary approach means that the actual **maximum residue limits – MRLs – are often thousands of times lower than the level at which any traces of a medicine would have any impact on consumer health.**

This booklet explains how safety measures such as MRLs are set and looks at other measures that guarantee that the food we eat is safe.



2. FOOD SAFETY ASSURED THROUGH MAXIMUM RESIDUE LIMITS

Discovering, developing and bringing a new veterinary medicine to market can take up to 12 years and costs more than US\$100 million or €70 million. Huge amounts of data establishing the quality, safety and efficacy of a product must be generated during the development process.

Where a product is intended for use in food-producing animals, additional information, including comprehensive food safety data packages, must be submitted to regulators. These show the level at which traces of the medicine (referred to as

residues) are present in edible animal tissue as well as products such as milk and eggs, and the rate at which these residue levels decline after an animal has been treated with the medicine.

This information allows regulators to calculate maximum residue limits, MRLs, which must be established for each veterinary medicine used in food-producing animals before it is allowed to be administered to animals.

2. FOOD SAFETY ASSURED THROUGH MAXIMUM RESIDUE LIMITS

How MRLs are calculated for veterinary medicines:

1

NO OBSERVABLE ADVERSE EFFECT LEVEL (NOAEL):

The first step in the MRL process involves establishing the highest dose of a medicine, in a range of test-animal species, that is without any ill effects.

This is identified by very well defined tests over long periods, in which a product is administered to animals at increasing doses – often with a factor of ten between each dose level (for example, 10, 100 and 1000 mg/kg bodyweight). If adverse effects are observed in animals dosed at 1000 mg/kg but not at 100 mg/kg, then 100 mg/kg is deemed to be the highest dose level at which no adverse effect occurs. This is called the ‘no observable adverse effect level’, or NOAEL. In reality, the actual dose at which effects begin to occur will lie somewhere between 100 mg/kg and 1000 mg/kg.

This means a safety margin that could amount to a factor of up to 10 has already been built into the calculation. This is just one of the many safety factors used in this part of the safety process.

2

ACCEPTABLE DAILY INTAKE (ADI):

The NOAEL is used to calculate an Acceptable Daily Intake (ADI) – the amount of a substance that could be consumed by a person every day over an entire lifetime without posing any appreciable health risk.

To arrive at the ADI the NOAEL is normally divided by a series of safety factors: a factor of 10 to allow for differences in the susceptibility of individual animals to the medicine, and by a further factor of 10 to take into account the differences in sensitivity that may exist between species. This ultimately assures that it is safe for humans too. It means the ADI, expressed as amount per kilogram body weight, is at least a hundred times lower than the NOAEL.

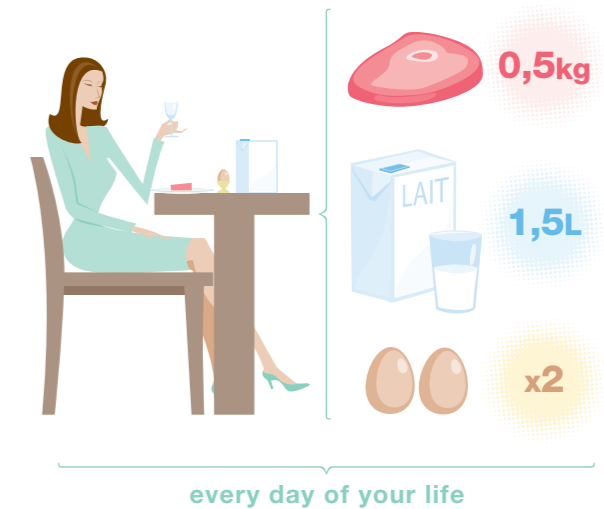
Sometimes regulators add an additional safety factor (up to 10) to account for potential uncertainties, - either for uncertainties in available data or to account for special circumstances - which could make the ADI up to a thousand times lower than the NOAEL. All of these factors make sure that the approved acceptable level is very conservative.

3

MAXIMUM RESIDUE LIMIT (MRL):

The final step in the process involves dividing the ADI up among the various products from a treated animal that may enter the food chain (i.e., liver, kidney, muscle, fat, milk, eggs, etc), and establishing an MRL for each of those products. In doing so, regulators take into account several factors, including the amount of traces of medicine in different tissue types once a drug has been given to an animal, and how much of a particular food is likely to be consumed on a daily basis.

Again, MRLs are set at levels so that even if all of the food that we eat contained traces of medicine at the maximum allowed level, the acceptable daily intake (which can be up to a thousand times below the level at which traces could have an impact on consumers' health) would still not be exceeded.



ALL THESE CALCULATIONS ARE CONSERVATIVE TO ENSURE HUMAN SAFETY. THEY ARE BASED ON THE ASSUMPTION THAT A PERSON'S DIET INCLUDES THE CONSUMPTION OF HALF A KILOGRAM OF MEAT, 1.5 LITRES OF MILK AND 2 EGGS, EVERY SINGLE DAY OF HIS OR HER ENTIRE LIFE.



3. WITHDRAWAL PERIODS

The amount of a veterinary medicine present in treated animals and their products, such as milk or eggs, declines over time as it is metabolised and is eliminated from the animal's body. Tests to establish the rate at which these levels decline are part of the food-safety data package that must be submitted by companies requesting permission to sell a new veterinary medicine for use in food-producing animals.

A withdrawal period is the amount of time that must lapse between the administration of a medicine and the point when the animal and/or its produce is/are allowed to enter the food chain to ensure that levels have fallen below the MRL. As explained before, the MRLs are set in such a way that they are significantly below any levels that were observed to have an effect, so no unsafe residues are found in food from animals treated with veterinary medicines.

The way individual medicines are metabolised by animals and the routes via which they are eliminated from the body vary widely. These variations are taken into consideration to assure that the residue in any individual animal tissue does not exceed the ADI.



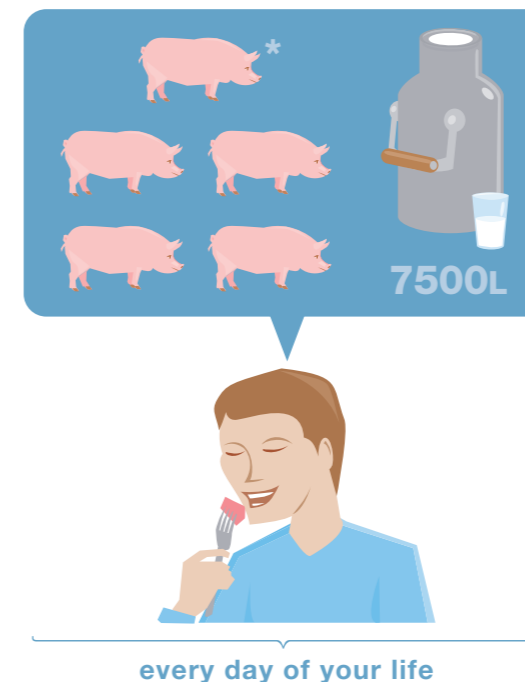
WITHDRAWAL PERIODS ARE INDICATED ON THE LABEL AND PACKAGING OF VETERINARY MEDICINES. BY COMPLYING WITH THE WITHDRAWAL PERIODS, WHICH THEY ARE LEGALLY REQUIRED TO DO, VETERINARIANS AND FARMERS PLAY THEIR PART IN ENSURING THE SAFETY OF ANIMAL MEDICINES AND OF OUR FOOD.

4. MONITORING

The final step in ensuring that our food is safe, and to make sure that residues of veterinary medicines in our food do not exceed MRLs, governments have systems in place that test many thousands of samples every year, and take action if any one has levels that are above the allowed limit. The results of these monitoring programs confirm the effectiveness of the control measures that are in place. In Europe the results of residues control plans are regularly published on the website of the European Commission²; in 2007 less than 0.3% were found to exceed the MRL in more than 700,000 samples. In the US, the USDA in 2007 tested nearly 21,000 random samples and found 42 violations of the established MRLs for a 0.2% violation rate.

If residues are found at levels in excess of the MRL, the animal produce (such as meat, milk and eggs) is not allowed to enter the food chain and the causes are investigated by government inspectors. Traceability schemes developed in many countries mean that identifying the source of the produce is simple: inspectors can visit the farm of origin to investigate the cause, and can provide farmers with advice on how to use medicines safely. In addition, governments have the power to take legal action against producers who fail to adhere to these strict standards.

² EUROPA > European Commission > DG Health and Consumers > Overview > at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm



* This applies to all species of food-producing animals, including fish, not just pigs.

FIGURES SPEAK FOR THEMSELVES

TO PUT SOME PERSPECTIVE ON ALL OF THESE SAFETY FACTORS, HERE ARE SOME QUICK EXAMPLES:

- FOR ONE VETERINARY MEDICINE USED IN SWINE, THE SAFETY FACTORS BUILT INTO THE SYSTEM WOULD MEAN THAT A CONSUMER WOULD HAVE TO EAT THE EQUIVALENT OF 5 WHOLE PIGS A DAY, EVERY DAY OF HIS LIFE, TO GET TO A LEVEL OF INTAKE OF RESIDUES THAT WOULD STILL BE BELOW THE NOEL.
- ALTERNATIVELY, A CONSUMER WOULD NEED TO DRINK 7,500 LITRES OF MILK EACH AND EVERY DAY OF HIS LIFE TO EVEN APPROACH THE NOEL FOR A VETERINARY MEDICINE USED TO TREAT AN ILLNESS IN A COW.



5. CONSUMER SAFETY - TOP PRIORITY FOR ALL

Even though there are a lot of numbers and elements to consider, the most important things to remember are:

- 1** Every effort is made to keep animals healthy. Sometimes they need veterinary medicines, just like people sometimes need medicines to stay healthy.
- 2** The use of all veterinary medicines is strictly regulated by governments and producers must stick to these regulations. The result are high quality veterinary medicines that are safe and efficacious against diseases in animals.
- 3** Multiple safety factors are in place to assure that products of animal origin such as meat, milk and eggs are safe for consumers. This means that there are no traces of medicines in animals that would pose any risk to consumers.
- 4** To make sure that residues of veterinary medicines in our food do not exceed MRLs, governments do regular monitoring.

**Food from animals is highly regulated,
and is an extremely safe source
of high-quality protein.**



6. FREQUENTLY ASKED QUESTIONS

What are residues of veterinary medicines?

After administration, a veterinary medicine may be detectable in the tissues of the treated animal.

These are known as residues. Over a relatively short period of time these are broken down and eliminated from the animal's body in the urine and faeces.

What is a Maximum Residue Limit?

A Maximum Residue Limit (MRL) is the highest concentration of a veterinary medicine, usually expressed in µg/kg (parts per billion), that is legally acceptable in food from animals that have been treated with a veterinary medicine.

Who sets MRLs?

MRLs are set by national and international committees of scientific experts, usually attached to the public authorities that regulate the use of veterinary medicines. At a global level, the Codex Alimentarius Commission establishes MRLs based on advice provided by the

FAO/WHO Joint Expert Committee on Food Additives (JECFA). Regulators in most developed countries either set their own MRLs or follow international standards, such as Codex.

How do we know MRLs are being observed?

Regulators test thousands of food samples every year, checking them for residues of veterinary medicines and a range of other substances.

Is food dangerous if it contains residues in excess of an MRL?

One of the reasons why there is a series of cumulative safety factors built into the use of veterinary medicines is to assure that even if, on rare occasions, a residue level occurs that exceeds the MRL, consumer protection is not compromised - so no, it is not dangerous.

There are also many efforts through education, label statements and discussions with producers to keep the

proper and safe use of veterinary medicines as a top priority. This includes training on proper use of these medicines and keeping to the withdrawal periods.

What happens when residues are found at levels above an MRL?

MRLs are designed with enough safeguards to ensure that isolated breaches, should they occur, will not enter the food chain and, therefore, will not compromise consumer protection. In addition, follow-up investigations are carried out whenever tests reveal traces of a substance at levels in excess of its MRL. Most of these are the result of accidental misuse or failure on the part of farmers to observe withdrawal periods. In such cases, regulators usually offer advice to farmers so that mistakes are not repeated.

Where more serious violations are found, regulators have the power to ban all sales of animals and animal produce from that particular farm.



7. ABOUT IFAH

The International Federation for Animal Health (IFAH) is an organisation representing manufacturers of veterinary medicines, vaccines and other animal health products in both developed and developing countries across five continents.

IFAH's mission is to foster a greater understanding of animal health-related matters and promote a predictable, science-based regulatory environment that facilitates the supply of innovative and high quality animal medicines, vaccines and other animal health products into a competitive market place.

These products contribute to a healthy and safe food supply as well as a high standard of health and welfare for animals and people.

TO FULFILL THAT MISSION, IFAH WILL:

- Act as the voice of the industry in dialogue with the major international bodies that have an impact on the animal health industry (OIE, FAO, WHO, Codex, WTO and others);
- Encourage and assist the development of predictable, science-based regulatory procedures and standards;
- Represent the industry with a unified, global voice in dealings with governments, food-industry partners and consumers; and
- Facilitate the international harmonisation of regulatory guidelines governing animal health products.



8. ACRONYMS

ADI - Acceptable Daily Intake

FAO - Food and Agriculture Organisation of the United Nations

JECFA - FAO/WHO Joint Expert Committee on Food Additives

MRL - Maximum Residue Limit

NOAEL - No Observable Adverse Effect Level

OIE - World Organisation for Animal Health

USDA - United States Department of Agriculture

WHO - World Health Organisation

WTO - World Trade Organisation

WP - Withdrawal Period

