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**Advise from the Director of the
Office for Risk Assessment and research to
the Minister of Health, Welfare and Sport
and the Minister for Agriculture**

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Risks to public health from horsemeat of unknown origin

Background

Horsemeat has recently been found in products for human consumption, without this having been declared on the label. The meat appears to have been processed into several products through various links in the horsemeat trade. The consignments of horsemeat concerned could have included meat originating from Romanian horses. This raises the question of whether the consumption of horsemeat poses a risk to public health.

The Minister of Health, Welfare and Sport, and the Minister of Agriculture therefore requested the Office for Risk Assessment and research (BuRO) of the Dutch Food and Consumer Products Safety Authority (NVWA) to assess possible risks to public health if food was consumed that contained horsemeat of unknown origin.

Action taken by BuRO

On 15 February 2013 a preliminary risk assessment was sent to the policy departments of the two Ministries and the NVWA was informed in connection with the ongoing meat and food chain investigation. BuRO immediately contacted the European Food Authority (EFSA) and the European Medicines Agency (EMA) in order to keep up to date with the latest developments. The Front Office for Food Safety of the institutes RIVM and RIKILT was asked to make an assessment of the veterinary medicines most likely to pose a risk to public health if residues of these products are present in horse meat.

The advise and recommendations are based on BuRO's management summary and letter report already sent to policy departments. For reasons of urgency a draft advise and recommendations are being sent today, 27 February 2013, and do not include peer reviews as is normal practice. The final advise will be submitted as soon as possible.

Findings

Chemical risks

The most serious chemical risks posed by horsemeat relate to veterinary drugs which horses may have been treated with. This is most likely to be the case if the meat was obtained from racehorses falsely designated as meat-producing animals. For reasons of food safety, horses for commercial food production can only be treated with one or two drugs. For most of these products a maximum residue limit has been set (MRL) for edible parts, including muscle meat. Meat containing residues under this limit is suitable for human consumption. For horses designated as pets, and which will therefore never be suitable for meat production, veterinary medicines are available for which no MRL has been set.

Veterinary medicines for which no MRL has been set

Phenylbutazone is a painkiller that is not permitted for use in meat-producing horses. The substance is used for clinical indications and as a means of doping. Phenylbutazone is also sometimes used as medicine by humans. It has several known side-effects. In humans phenylbutazone and the metabolite oxyphenbutazone can have toxic effects on bone marrow. A therapeutic dosage would cause harmful effects in approximately 1 in 30,000 patients. It is not known what dosage of phenylbutazone would cause these effects.

In Europe anabolic steroids may not be administered to animals used for commercial food production, including horses. However, these substances are sometimes given to racehorses for the purposes of doping, and if these animals are subsequently falsely designated for meat production, residues of these substances could be present in horsemeat.

BuRO concludes that horsemeat containing residues of the substances referred to is not suitable for human consumption as these substances may not be administered to animals in commercial food production. However, the risk is extremely low that toxic residues of phenylbutazone and the much less toxic steroids are present in horsemeat and therefore pose a risk to the consumer. Even if there is occasional exposure to these substances, this would be much lower than the dosage prescribed to human patients.

Veterinary medicines for which a maximum allowable limit has been set

Ivermectin is an anti-parasitic which is permitted in animals for commercial food production. If residues of this substance are detected, the question is whether the slaughter withdrawal period of 35 days has been adhered to. In Europe no MRL has been set for ivermectin in muscle meat. The MRL set in the United States is 10 µg/kg. If a normal dosage is administered and the slaughter withdrawal period is adhered to, ivermectin residues in meat are not harmful to humans.

Ampicillin is permitted for use on horses. An MRL of 50 µg/kg has been set for all parts intended for human consumption, including horsemeat. In susceptible people small dosages have been known to create an allergic reaction and there is a risk of resistance development from this and from residues of other antimicrobial substances.

Oxytetracycline may be administered to horses and has an MRL of 100 µg/kg in meat. Oxytetracycline and comparable antibiotics have low toxicity towards humans.

Trimethoprim-sulfadoxine and trimethoprim-sulfadiazine are permitted for use on horses. The 'Acceptable Daily Intake' (ADI) for trimethoprim is 12,5 µg/kg. In humans, these substances can inhibit blood production and may cause aplastic anaemia. Sulfonamides for which no ADI has been set, may lead to adverse reactions such as hypersensitivity in sensitive individuals such as HIV patients. The MRL for both trimethoprim and sulfonamides is 100 µg/kg, with trimethoprim used as marker.

Meat which exceeds the action limit recommended by BuRO for ivermectin and the MRLs indicated for antibiotics must be withdrawn from the market.

Microbiological risks

Horses reared in countries such as Romania where *Trichinella* spp. and *Toxoplasma* are relatively common are at increased risk of becoming infected with these parasites. Due to the severity of these diseases in humans, if consumed raw or undercooked, the meat from horses in which these parasites are present poses a significant risk to public health. Outbreaks in countries where horsemeat is often consumed raw such as Italy or France underline the occurrence of these parasites in horsemeat.

BuRO conclusions:

- the use of phenylbutazone or oxyphenbutazone in food producing animals is prohibited because these substances may have an adverse effect on public health in sporadic cases; therefore horsemeat containing residues of these substances is not fit for human consumption;
- horsemeat containing one or more residues of ivermectin, ampicillin, oxytetracycline, trimethoprim-sulfadoxine and trimethoprim-sulfadiazine for which the MRL or action limit has been exceeded is not suitable for human consumption;
- the likelihood of the presence in horsemeat of toxic residues from phenylbutazone or oxyphenbutazone, and/or from the much less toxic veterinary medicines for which an MRL is established is very low;
- it is unlikely that a consumer would frequently consume contaminated horsemeat as the meat in question has been processed, and the health risk for the consumer is therefore extremely low;
- consumption of raw or undercooked horsemeat may cause a severe food infection such as trichinosis or toxoplasmosis.

BuRO Advise and recommendations:

To the Minister of Health, Welfare and Sport and Minister for Agriculture

1. Strict enforcement of the zero tolerance policy for phenylbutazone and its metabolite oxyphenbutazone in horsemeat.
2. Periodic repetition of controls to detect equine DNA in meat, meat preparations and meat products, with particular attention to food products that are consumed raw such as steak tartare and ox sausage.
3. Risk-based determination of the residues in horsemeat indicated in this report and ensure analysis of phenylbutazone should also cover residues of the toxic metabolite oxyphenbutazone.
4. Ensure the investigation not only covers meat from horses reared in the Netherlands but also particularly horsemeat from other Member States and third countries.
5. Zero tolerance for horsemeat containing residues of banned substances such as phenylbutazone. Market withdrawal of horsemeat containing residues of permitted substances for meat-producing animals that are above the MRL.
6. It is advisable to again remind the public of the risks of consuming undercooked meat, including horsemeat, particularly for risk groups such as pregnant women.
7. Analyse the nature and scope of the risk factors that play a role in horse registration and the data about medication administered.
8. Study the possibilities for alternative identification methods such as DNA identification of horses used as pets to prevent fraudulent activities such as false designation of horses.

Annex 1

Investigation into the risks of horsemeat of unknown origin to public health

Background

Lasagne offered for sale in a retail outlet has been found to contain horsemeat instead of beef as indicated on the label. The meat proved to have originated from Romanian horses and had passed through various links in the commercial food chain including a Dutch meat company, and processed into lasagne by a company in Luxembourg. This finding raised the question of whether horsemeat – which is cheaper than, say, beef - could also be present in other meat preparations or meat products. This issue is raised not only because consumers could be misled, but also because of potential risks to public health.

The request for risk assessments

In light of the above findings, the Minister of Health, Welfare and Sport (VWS), and the Minister for Agriculture asked the Office for Risk Assessment (BuRO) to:

"Assess the risk to public health of the possible presence of phenylbutazone and other veterinary drug residues and pathogens in horsemeat".

Action taken

In view of the urgency of the problems, BuRO made a provisional assessment on Friday 15 February 2013 of the potential risks to public health. This provisional assessment was sent by post to the policy departments of Health, Welfare and Sport (VWS) and Economic Affairs (EZ). The Deputy Inspector General of the NVWA was also informed of the contents of the provisional risk assessment, in connection with the investigation in the chain meanwhile launched by the NVWA. The House of Representatives was informed of the NVWA investigation in a letter of 14 February 2013. On 15 February BuRO asked the Food Safety Front Office of the National Institute for Public Health and the Environment and the State Institute for Quality Control of Agricultural Products (RIVM and RIKILT) to provide further information on the chemical risks of horsemeat. In the first instance the focus was on in the painkiller, phenylbutazone, which had incidentally been found in horsemeat in the United Kingdom and elsewhere. Subsequently the Front Office was asked to assess the main risks of residues of ivermectin and some antimicrobial drugs.

On 15 February 2013 BuRO consulted the EFSA database concerning residues of phenylbutazone and sent these data directly to the Front Office. On 19 February BuRO contacted the Dutch subject expert at the European Medicines Agency (EMA), who is also vice-president of the Committee for Medicinal Products for Veterinary Use (CVMP), for information on the joint initiative of EFSA and EMA to publish a "statement on phenylbutazone in horsemeat" on Friday 22 February. On Wednesday 20 February BuRO, the Front Office and EMA exchanged substantive views on the risk of phenylbutazone in horsemeat.

The same day, BuRO (NVWA), at the request of EMA and EFSA, submitted data on phenylbutazone within the framework of the National Residues Control Plan (NRCP). On 21 February BuRO sent a management summary of the draft advisory report to the policy directors of the two Ministries (VWS and EZ).

The peer reviews will be incorporated as soon as possible into this advisory report, which in view of the urgency of the situation is being sent today, 27 February 2013

Risk assessment

Risks and the nature of the risks

The sale of horsemeat and horsemeat products is not prohibited by legislation provided the products are properly labelled. If horsemeat is produced and processed according to the rules then there are no particular public health risks associated with horsemeat and horsemeat products. Horses, like other farm animals, can carry pathogens and contain chemical substances including veterinary medicines, which can be transmitted to humans by various means, including consumption of the meat. There are regulations and laws designed to limit the risks, which the NVWA supervises in the normal production-consumption chain. As part of the regulation of the chain, clear labelling of horsemeat and horsemeat products is required. Incorrect labelling can be an indication that the meat or meat products are of dubious origin. These considerations provided the impetus for this report. In the case of products where horsemeat was not listed on the label, but nonetheless contained horsemeat, the production-consumption chain was no longer transparent. The origin of the horsemeat was not clear, so there could be no clarity about the safety of the horsemeat. For this reason BuRO designed a broad risk assessment to review a broad spectrum of public health risks. At the same time BuRO took into account the fact that horsemeat of unknown origin had as yet only been used in prepared foods in which the amount of horsemeat was probably very limited. BuRO also took account of the unlikelihood of consumers being frequently exposed to contaminated horsemeat.

Microbiological risks

The nature and scale of the microbiological risks associated with horsemeat are determined by the prevalence of zoonotic agents in the country where the animals were born and bred, as well as the hygiene in the slaughter process and the care with which the postmortem inspections are conducted.

Chemical risks

The chemical risks associated with horsemeat are partly determined by the origin of the animals. For example, in certain areas with high concentrations of, say, heavy metals or dioxins can cause increased levels of these substances in the meat and offal of horses that are relatively free ranging.

The presence of drug residues has less to do with place of origin and far more to do with the use of the horse (as a pet, for meat or for sport). In principle horses are intended for meat production unless their horse passport indicates otherwise. Only a limited number of registered drugs are specifically authorised for use in horses intended for meat production.

The veterinary surgeon treating a horse therefore has the option to use other drugs on a horse intended for meat production, provided such drugs are already authorised for use in other food-producing animals ("cascade" use). In that case the minimum withdrawal period prior to slaughter is 28 days from the last treatment, unless the drug information leaflet indicates otherwise.

All other drugs are prohibited for use in horses. An exception to this ban is made for horses designated in their passports as domestic pets. Any amendment of the designated use of "meat production" is final and irrevocable. Any drugs administered must be recorded in the passport by the responsible veterinarian. Veterinary medicines that are only authorised for sport horses must therefore not be found in horses for consumption, and partly for this reason, no Maximum Residue Limits (MRLs) are set for the edible parts (MRL). Illegal reclassification of sport horses as horses for meat production could in some cases lead to the presence of such medicines in horsemeat.

The nature of the supply chain

Complex trade chains are well known in the production of food of animal origin. The complexity of the process whereby, in a relatively short time, batches of meat are cut, processed and offered for sale, raises issues about the practicability and reliability of the compulsory 'tracking and tracing' system. Horsemeat comes from animals that fall outside the compulsory I&R system that applies to many other farm animals. The [horse] identification system is limited to an accompanying passport or a transponder, which, unlike individual external marking, leaves scope for fraud such as the doctoring of passports and failure to record veterinary medication.

The associated potential risks to public health consist in toxic residues and pathogenic agents, the source of which is traced as quickly as possible to prevent further exposure of consumers if possible. The lack of conclusive identification and labelling of meat and meat products also makes it difficult to carry out efficient risk-based monitoring.

Microbiological risks of horsemeat

Like other farm animals, horses can carry pathogens that may already be present in the meat, but can also be transmitted to the meat during slaughter.

Essentially when it comes to the level of contamination, the type of micro-organisms or parasites and the associated risks to public health, there are no great differences between horsemeat and other types of meat from animals from the same country.

Pathogen levels in the environment and sometimes in animals can vary from country to country and region to region, depending partly on the way that animals are kept. This is apparent from the EU's annual pathogen reports and other sources.

Consequently any assessment of the microbiological risks must take account of the country in which the horses were raised. The risks are also significantly affected by how much the meat is heated prior to consumption, and so by regional customs of eating certain types of meat in the raw state.

For example pork is eaten raw on a fairly large scale in Germany, and it is not uncommon to eat raw horsemeat in France and Italy. Products marketed in the Netherlands as "ready-to-eat", such as filet américain and ox sausage, into which contaminated horsemeat is processed, could thus present a risk.

Pathogens in horses and horsemeat

In contrast to other production animals, there is no systematic data collection on pathogens in horsemeat that are transmissible to humans (zoonoses). Summary data on known agents of food infections that can be present in horses are shown below.

Pathogenic *Escherichia coli*

Ruminants are regarded as a natural reservoir of pathogenic *Escherichia* (*E.*) *coli*, including STEC/EHEC. In recent years the *E. coli* Reference Center (ECRC) in the USA has found no O157:H7 in more than 600 *coli* isolates from horses. The bacteria are incidentally found in foals, but scarcely at all in healthy adult animals, so faecal samples are not tested for the presence of pathogenic *E. coli* [1].

Listeria monocytogenes

As with human pathogenic *E. Coli*, ruminants are regarded as reservoirs of *L. monocytogenes*, an ubiquitous bacterium. In tests, the bacterium was found in the faeces of over 14% of clinically healthy cattle. Listeriosis occurs in horses, but is rare in comparison with other horse diseases [2]. It is not likely that horses are carriers, but nor can it be ruled out. In comparison with other sources of food contamination, such as contaminated surfaces, it is highly unlikely that *L. monocytogenes* is a substantial contributor to human listeriosis.

Campylobacter spp.

Incidental cases of gastro-enteritis in horses are known to have been caused by the campylobacter species. The bacterium can be found in young animals, but carrier traits and excretion of the bacteria have never been described in healthy adult horses. Campylobacter on horsemeat does not seem to present a risk to human health compared with other foods of animal origin.

Salmonella spp.

The majority of food infections with *Salmonella* spp. come from chicken and pigmeat and contaminated eggs. The production animals concerned show few if any symptoms of disease, and are therefore designated as carriers. Horses are scarcely, if ever, carriers. Salmonellosis is a serious disease in horses which requires veterinary treatment. Two to eight percent of infected horses excrete the bacteria with the faeces, but in the majority of horses the excretion ceases after a month [3]. Meat from horses slaughtered during the excretion period could be contaminated with the bacteria. However, the contribution of salmonella in horsemeat to salmonellosis in humans is extremely small in comparison to other sources.

Cryptosporidium parvum

This parasite occurs commonly in young horses but is scarcely, if ever, found in adult animals. The risk of *C. parvum* in horsemeat is therefore extremely low.

Giardia duodenalis

Like *C. parvum* this parasite is often associated with food infections contracted through contaminated drinking water or vegetables that have been sprinkled with contaminated surface water. Around 6% of the tested horses proved to excrete *G. duodenalis* with the faeces, but there is no evidence to date of the zoonotic nature of the parasite in horses and, partly for this reason, the risk of this parasite on horsemeat is limited.

Trichinella spp.

If inadequately heated before consumption, contaminated meat of various animal species, including horses, may cause trichinellosis in humans. Given the severity of the disease the presence of the parasite in meat poses a great risk. The risk of meat being contaminated with trichinella is largely determined by the prevalence of the parasite in the intermediate hosts such as mice (domestic and sylvatic cycle). This cycle is limited in many European Member States and consequently some countries have been accorded trichinosis-free status. In Eastern European countries such as Bulgaria and Romania however the parasite is still commonly found in production animals such as pigs. Horses are also susceptible to trichinella infection. In countries where there is a substantial cycle one can assume that horses run a higher risk of infection. One of the aims of the postmortem inspection of production animals, including horses, is to detect trichinella and other infections. However, the reliability of the trichinoscopy detection method still used in some countries is questionable.

The incidence of trichinellosis in countries with a substantial cycle is thus extensive. The report 'Worldwide occurrence and impact of human trichinellosis 1986-2009' shows that Romania had the highest incidence among European countries in that period with over 50% of all reported cases in Europe [4]. Regional differences in incidence can sometimes be explained by dietary customs. For example, the relatively high number of cases of trichinellosis in Transylvania, a region in Romania, was attributed to the local habit of eating raw pigmeat [5,6].

Various reported outbreaks of trichinellosis have been linked to the consumption of horsemeat. Around 60% of European consumption of horsemeat takes place in France and Italy. There were twelve reported outbreaks in these countries from 1975-1998 with almost 3000 cases of illness, probably because horsemeat is often eaten raw in Italy and France [7]. In five of these outbreaks the horses originated from Eastern Europe and in the remaining cases from the United States, Canada, Mexico, Poland and Yugoslavia [8].

Toxoplasma gondii

This parasite can be found in several species of production animals following ingestion of infectious oocysts excreted by cats. Recent serological data (IFAT and MAT) collected in Brazil provide useful insight into the infection levels of different species. In this study 7 of the 16 horses (43.7%) proved seropositive. Of the sheep tested, over 60% were positive, while the number of seropositive cattle was far lower at 3% [9].

In the USA and Canada a seroprevalence of 6.9% was found in food-producing horses [10]. In Romania there was 50% toxoplasma seroprevalence (ImmunoComb ELISA) in cats from 6-24 months, while the seroprevalence in sheep varied from 30-70% [11].

It is difficult to compare these Romanian data with the seroprevalences in animals from other countries. The most important conclusion to be drawn is that production animals in Romania are very regularly exposed to infectious oocysts in the environment.

Humans can acquire an infection through ingestion of oocysts from the atmosphere or through toxoplasma-contaminated meat or meat products. A comparative study among young adult women in various countries shows wide variations in seroprevalence. In 2004 a prevalence of 35.2% was measured in the Netherlands, while the seroprevalence in Romania in 2008 was 57.6%.

An extra risk can arise if imported horsemeat is contaminated with genotypes of toxoplasma with a relatively high infective capacity. In 2011 atypical, particularly virulent *T. gondii* genotypes were found in three patients who had probably acquired them by eating raw horsemeat from Brazil and Canada [7].

Antimicrobial resistance

Antibiotics are not prescribed as a herd treatment for horses as they are for other production animals such as pigs and poultry. It is therefore anticipated that the resistance problems will be of a different order in horses than in other production animals. For example, in the case of MRSA it is known that the bacteria is commonly found in horses, but in all probability the problems associated with MRSA and other resistant bacteria will not reach the same proportions as in other production animals. Consequently it is anticipated that the risks of resistant bacteria on horsemeat will not be substantial.

Chemical risks of horsemeat

Environmental contaminants

Horses that graze on contaminated land, or are fed with products from that land, can be contaminated with substances such as heavy metals and dioxins. The extent of this depends partly on the type of substance, the concentration in the soil and crop, and the absorption of the substance from the intestine. Indicators from the areas where the horses were pastured can offer insight into the extent to which these substances could exceed the prescribed standards in food. These specific risks are being disregarded in this context for the time being since the exact origin of the horses is unknown.

Veterinary medicines

Chemical risks can also arise from veterinary medicines administered to horses. Horses are classified in the legislation as animals whose meat is intended for consumption unless otherwise specified in the passport. Partly for this reason, only a limited range of veterinary medicines is authorised for use in horses.

In the absence of an adequate drug, the cascade system allows the veterinarian to use drugs authorised for use in other food-producing animals.

In that case the minimum withdrawal period for horses prior to slaughter is 28 days from the last treatment, unless the drug information leaflet indicates otherwise.

All other substances are prohibited for horses intended for meat production. Their use is only permitted if the designation of the horse is amended to "domestic pet". The veterinary surgeon must record this change in designation, along with the medications administered, in the passport. The change in designation is irrevocable. Once a horse is officially classified as a domestic pet it can never again be destined for normal meat production.

Residues in horsemeat of substances that are not approved for food-producing horses can therefore be the result of illegal use of these substances in food-producing horses or of legal use in domestic animals which are later illegally re-classified as food-producing animals (by falsifying the passport).

Phenylbutazone

Phenylbutazone is a nonsteroidal anti-inflammatory drug (NSAID) used for the treatment of pain. The use of phenylbutazone on food-producing animals is banned as it cannot be ruled out that residues of this substance may pose a public health risk. The pain killer is only administered to individual animals and not as a group medication. Furthermore, this substance may only be used on pets such as race and sports horses, and if these animals are illegally redesignated as slaughter animals, residues of the pain killer may be present. However, contamination of the whole slaughter batch is highly unlikely.

Phenylbutazone injections may only be intravenously administered to horses as the drug can cause tissue damage. The intravenous dose is 4.4 mg/kg phenylbutazone per day, for a maximum period of 5 days. In the United Kingdom there is a formulation of the drug that may be orally administered in a double daily dose of 4.4 mg/kg.

The half-life of phenylbutazone in horses is 5-6 hours, although when assessing the risks it should be considered that the substance is quickly metabolised to oxyphenbutazone which is estimated to be equally as toxic as the parent compound phenylbutazone. BuRO has established that the metabolite oxyphenbutazone cannot be detected through the prescribed method.

Analyses of the concentration gradient of phenylbutazone in the tissue of horses after a regular dose has been administered are scarce. In view of the drug's kinetics, the highest concentrations are estimated to be present in the kidneys, followed by the liver. Twelve hours after an intravenous dose of 4.4 mg phenylbutazone/kg, the highest concentration in muscle tissue was 0.5 mg/kg and when measured again after twelve hours the concentration had decreased to <0.1 mg/kg [12].

In a worst case scenario prepared by the RIVM-RIKILT front office, after the administration of 8.8 mg/kg phenylbutazone, the total concentration of phenylbutazone and oxyphenbutazone in equine muscle tissue can reach 13 mg/kg (Annex 2).

No MRLs are set for phenylbutazone in food products. This means that even low concentrations are not permitted to occur in food products of animal origin. Phenylbutazone and oxyphenbutazone are also for example chloramphenicol, toxic to the bone marrow, which in humans may lead to disturbances in the ratio of the normal components of blood or aplastic anaemia. These effects are described in the therapeutic use of phenylbutazone in humans, and occurred in approximately 1:30,000 patients. It is not possible to determine the concentration of phenylbutazone and oxyphenbutazone that would produce these effects. The toxicity for liver and kidneys has been determined in laboratory animals and there is evidence of carcinogenicity (Annex 2).

The risk of residues in horse meat has been determined by the front office in a worst case scenario in which the meat contains 13 mg/kg phenylbutazone and oxyphenbutazone. Consumption of 100 grams of this horsemeat would result in a dose of 0,37 µg/kg in an adult of 60 kg. This dose is 227 times smaller than the therapeutic dose used in humans: 5 mg/kg. A child of 15 kg that consumes 100 grams of horsemeat contaminated with phenylbutazone and oxyphenbutazone would be subject to a dose of 6 µ/kg. This is 56 times lower than the therapeutic dose for humans (Annex 2).

Anabolic steroids

The European Commission has banned the use of 17-β estradiol, testosterone, progesterone, zeranol, trenbolone and MGA as growth promoters. Use of medicines containing these substances is only permitted on the basis of clinical indicators.

In the USA however, such substances are permitted as growth promoters for food-producing animals. Anabolic steroids, including boldenone, nandrolone and testosterone can be administered to racehorses under certain conditions and limits have been set which must not be exceeded. Following illegal reclassification of racehorses residues of these substances can therefore be present in the meat. Many anabolic steroids occur naturally in humans and animals and concentrations will not reach toxic levels in meat.

Antiparasitics and antibiotics

Data on antiparasitic substances and various antibiotics used in horses are particularly scarce. The NVWA is currently conducting a study into the horse chain, looking at residues of these substances as well as phenylbutazone. MRL values or action limits are established for most veterinary medicines that are authorised for use in food-producing animals on the basis of the maximum concentration that can be ingested by a human in a day without adverse effects (ADI).

The antiparasitical drug, ivermectin, is authorised for use in food-producing animals. If residues of this drug are found the issue is whether the 35-day

withdrawal period was observed following normal administration of the drug. There is no [established] Maximum Residue Level (MRL) in Europe. In the USA there is an MRL of 10 µg ivermectin/kg. Residues of ivermectin in horse and other meat, certainly following normal dosage, are not toxic to humans. BuRO takes that view that the American MRL could be used as the action limit for muscle meat.

Meat, including horsemeat, that contains less than the established MRL or adopted action limits can safely be consumed (Annex 3). If the action limit for ivermectin and the MRLs for antibiotics in horse or other meat are exceeded the meat must be removed or kept from the market.

Answers to the questions

Question: What are the risks to public health of the possible presence of phenylbutazone in horsemeat?

Phenylbutazone is not authorised for use in food-producing animals because there is a possibility of toxic effects in sensitive patients. Residues in meat are the result of illegal use of the substance. Phenylbutazone is also sometimes used as a human medicine, and has various known side effects. A worst-case scenario of consumption of horsemeat of unknown origin in which residues of the painkiller phenylbutazone are present in high concentrations, indicates that the dose ingested with 100 gram of heavily contaminated horsemeat amounts to only a fraction of the usual dose that doctors prescribe to patients. However the lowest dose of phenylbutazone that could produce adverse effects (NOAEL) is unknown. The risk associated with these substances is thus not negligible. However, the risk of toxic residues of phenylbutazone and oxyphenbutazone being present in horsemeat, and consequently the risk to consumers, are assessed as extremely low.

Question: What are the risks to public health of other residues of veterinary medicines in horsemeat?

Meat, including horsemeat, that contains less of a certain veterinary medicines than the established MRL or adopted action limits can be safely consumed. If the action limit proposed by BuRO for ivermectin and the MRLs for antibiotics in horse or other meat are exceeded, the meat must be removed or kept from the market.
Question: What other risks does horsemeat pose to public health?

The microbiological risks of the known bacterial agents of food infections in horsemeat such as *Salmonella* spp., *Campylobacter* spp. *Listeria monocytogenes* and human pathogenic *Escherichia coli*, are certainly no greater than the risks of these agents in other meat species and products. However, this does not apply to *Trichinella* spp. or *Toxoplasma* in horsemeat from horses raised in countries where there is a substantial risk of infection with these pathogens. Adequate heating will also kill these pathogens, but if contaminated horsemeat or horsemeat products are eaten raw, rare or half-cooked, there is a considerable risk, not least in view the severity of these infections in humans.

The presence of environmental contaminants in the countries or regions in which the horses were raised could lead to higher concentrations in, say, the kidneys (heavy metals) or fatty tissue (dioxins).

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Yours faithfully,

Dr Antoon Opperhuizen
Director, Office for Risk Assessment and Research

**Office for riskassessment
and research**

Onze referentie
NVWA/BuRO/2013

**Risks to public health from
horsemeat of unknown
origin**