EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Deputy Director General

Brussels,
SANCO(D4) NG-NM/vs D(2008) 441413

Embassy of Andorra
Rue de la Montagne 10, bte 1,
1000 Brussels

Dear Sir/Madam,

Subject: Imports of equine meat from third countries

The purpose of this note is to inform you about the conclusions of an evaluation of the current situation regarding the food safety standards for the import of equine meat into the Community in relation to residue controls. The evaluation has been based on evidence gathered in audits of residue control systems in third countries carried out by the Commission inspection service (Food and Veterinary office (FVO)) located in Grange (Ireland). Equine meat includes meat of horses, donkeys, zebras and their cross-breeds.

FVO audits have found that in the majority of third countries veterinary medicinal treatment records for horses are not kept and there are no systems in place for segregating equidae intended for food production from other equidae. It has also been seen that certain third countries authorise or tolerate the administration to equidae of substances which are either expressly prohibited or are not authorised for use in equidae intended for food production in the Community.

As a consequence, equidae and equine meat are not necessarily produced under conditions which would allow their continued importation to the European Community for food purposes. With this letter the Commission wishes to clarify Community import requirements for equidae and equine meat and to allow meat exporting third countries to comply fully with EU legislation. The following clarifications do not affect in any way third countries' existing obligations to implement a residue monitoring plan and submit this on an annual basis to the Commission services for approval.

The Commission services are anxious to facilitate the necessary corrective measures to ensure compliance with our import requirements. **Therefore it is proposed to constantly reassess the situation during the following three years, during which third countries are expected to strengthen their control systems.**

Third countries are expected to implement the following measures covering a **minimum control period of six months before slaughter** of equidae, meat from which is intended for export to the Community:

- Equine animals intended for food production should be **identified** and a system of identity verification should be established.
- **In third countries where anabolic steroids are marketed for fattening purposes,** there should either be a prohibition on the administration of anabolic steroids for growth promotion purposes to *all* equidae or there should be a separate system for equidae which may be slaughtered for export of equine meat to the Community. This would require that equidae intended for meat production for the Community would be identified and segregated from those equidae treated with anabolic steroids for fattening.
- **Treatment records**. The purpose of recording treatments of animals with veterinary medicinal products is to ensure that animals are not slaughtered within the withdrawal period of the medicine in question, thus providing guarantees that the Community Maximum Residue Limit (MRL) for the particular pharmacologically active substance is respected. In the Community farmers are required to keep records of medicines. In addition for equidae in the Community, there is an equine passport which has a specific section for recording treatment with so-called 'essential' veterinary medicinal products for equidae, for which there is a mandatory 6 month withdrawal period. On that basis it is expected that treatments with veterinary medicinal products should be recorded on a document linked to and accompanying the identified animal when moving from one premises to another or to the slaughterhouse (food chain information).
- At the time of moving the animal to the slaughterhouse, the **competent authority** of the third country should be able to guarantee, at least for a period of not less than 6 months prior to slaughter of the equine animal, that the required **withdrawal periods** for veterinary medicinal products administered to the animal and recorded in the food chain information have been respected.
- The third-country exporting equine meat should set up a **risk based programme for controls** on the use of veterinary medicinal products and substances prohibited for use in the Community. The control programme should include regular inspections on holdings, collection centres and at slaughterhouses.

In order for the Commission services to be able to assess the implementation of these measures, third countries intending to export equine meat to the Community should **within three months of the date of this letter**, submit an action plan to the FVO. This plan should describe how the minimum set of measures referred to above will be implemented and the timelines for so doing. All of these measures should be in place within one year of the date of this letter. From that time, only horses with a register of medicinal treatments covering a period of six months prior to slaughter should be allowed to be slaughtered for export to the Community. This means that recording of treatments must start within **six months** of the date of this letter.

The Community will then reconsider the abovementioned measures and, if appropriate, make the necessary amendments in order to continue ensuring that food safety standards applied in exporting third countries meet Community requirements.

Those third countries which have submitted action plans to the FVO will be required to submit annual updates on the implementation of these action plans when submitting their residue monitoring plans to the FVO for technical assessment. Where appropriate, the implementation of these action plans will be inspected on the spot by the FVO.

For wild equidae (only zebra meat allowed), the provisions as laid down for wild land mammals would apply. These provisions foresee the submission of an annual residue monitoring plan which is restricted to the analysis of environmental contaminants (e.g. heavy metals).

Background data on the requirements for production of equine meat in the Community, the Community food safety policy, its objectives and measures to achieve these objectives are included in the appended annex.

Yours sincerely,

Paola Testori Coggi

CC: CVOs in Member States, Iceland, Norway and Switzerland.

Annex

BACKGROUND INFORMATION ON REQUIREMENTS FOR EQUINE MEAT IN THE COMMUNITY

Summary

In the Community, equidae are food producing animals which are identified by means of an identification document (*"passport"*). The passport also allows records to be kept of the administration of certain veterinary medicinal products. The passport permits the *exclusion* of individual equidae from the food chain in order to ensure that equidae destined for human consumption only receive medicinal treatments in accordance with Community legislation on food safety. Since 2000 the Community has reinforced the measures to verify the identity of equidae. Community legislation requires furthermore the keeping of individual treatment records on the holdings to ensure that withdrawal periods for veterinary medicinal products are respected. The inspection service of the European Commission's Directorate-General for Health and Consumers, the Food and Veterinary Office (FVO), monitors the implementation of these measures in Member States through regular audits and inspections.

1. Community objectives

The Community has identified two main food safety objectives for equine meat, which also apply to live equidae imported into the Community **for slaughter**:

- **Equine meat** must not contain residues of veterinary medicinal products (pharmacologically active substances) and contaminants exceeding Community maximum residue limits / levels.
- **Equine meat** must not be derived from animals which have been treated with substances prohibited for use in food producing animals in the Community.

2. Community food safety policy and measures to achieve food safety objectives

In the Community specific legislation ensures that veterinary medicinal products are only authorised if the potential residues of substances contained therein have been evaluated as safe. This legalisation also applies for products to be used in equidae. Control systems are required to verify the proper distribution and use of veterinary medicinal products. Regarding residues of pharmacologically active substances in food products derived from animals, the Community food safety measures which are in place can be classified as follows:

- Authorisation of veterinary medicinal products after a risk assessment and setting of MRLs for the pharmacologically active substances contained therein;
- Obligations and control measures concerning;
  - the distribution and use of veterinary medicinal products;
  - holdings (animal identification, treatment records etc.);
  - residues of pharmacologically active substances and contaminants (annual residue monitoring programme of Member States).

The key measures and the relevant Community legislation are as follows:

Marketing authorisation, production and distribution of veterinary medicinal products: Directive 2001/82/EC sets the framework for the marketing authorisation, production and distribution of veterinary medicinal products. A marketing authorisation can only be granted after a human safety evaluation of the pharmacologically active substance has been carried out according to Council Regulation (EEC) No 2377/90. A marketing authorisation is granted for treatment of a specific condition in one or more animal species.

Under specific conditions detailed in Article 11 of that Directive it is possible to use veterinary medicinal products in species other than those for which the medicines are authorised ("off label use").

Additionally and specifically for equidae, Commission Regulation (EC) No 1950/2006 established a list of "essential substances" to be used under the conditions and control instruments laid down in Article 10(3) of Directive 2001/82/EC in cases where no veterinary medicinal product is available for a condition in equidae. The use of these essential substances is by definition "off label" and is in accordance with Article 11 of Directive 2001/82/EC ("cascade " system).

Prohibited substances: Council Directive 96/22/EC prohibits or restricts the use of beta-agonists and of certain substances having a hormonal or thyrostatic action. Council Regulation (EEC) No 2377/90 in conjunction with Directive 2001/82/EC prohibits the use of substances mentioned in Annex IV of the Regulation.

Article 11 of Regulation 178/2002 (Food Law) requires that food imported in the Community is produced under conditions which are at least equivalent to those in the Community. Article 29 of Council Directive 96/23/EC requires that third country guarantees must have an effect at least equivalent to those provided by that Directive and Article 11 of Council Directive 96/22/EC prohibits the import by Member States of meat from animals to which hormones have been administered for growth promotion. Products derived from animals treated with substances prohibited in the Community cannot be considered as having been produced under conditions equivalent to those in the Community. Import of such products is not permitted.

Identification of equidae: Commission Decisions 93/623/EC and 2000/68/EC require that equidae are accompanied by an identification document ('passport') during their movements. The introduction of this system has been driven by, amongst other things, the need to protect consumers from harmful residues present in food obtained from equidae treated with pharmacologically active substances. The provisions concerning the identification of equidae have been strengthened by the recently published Commission Regulation (EC) No 504/2008 which enters into force on 1 July 2009 and repeals the above decisions on that date.

Treatment records and withdrawal periods:

Community legislation[51] requires the compilation of information relevant to the treatment of equidae with veterinary medicinal products, e.g. the date and nature of any prescribed treatment and of the administered substance, the identification of the animals and the withdrawal period required.

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[51] Directive 96/23/EC, Art. 10; Directive 96/22/EC Art. 4, Art. 5a; Directive 98/58/EC, Annex, point 5 and 6; Commission Decision 2000/68/EC, Directive 2001/82/EC Art. 10 and 69; Regulation (EC) No 853/2004 Annex II, Section III, part 3(c) (page 38); Commission Regulation No 1950/2006.

Withdrawal periods for veterinary medicinal products are part of the authorisation according to Directive 2001/82/EC. They need to be sufficiently long to ensure that MRLs established in Regulation 2377/90 are not exceeded.

In case of "off label use", the veterinarian specifies an appropriate withdrawal period. Unless the medicinal product used indicates a withdrawal period for the animal product concerned, the specified withdrawal period shall not be less than 28 days for meat from mammals (including fat and offal). In case of treatments with substances listed in Commission Regulation (EC) No 1950/2006 ('essential substances'), the withdrawal period shall be six months.

If substances prohibited for use in food producing animals are administered to equidae those animals *must* be excluded from the food chain in accordance with Article 6(3) and 10(2) of Directive 2001/82/EC.

Residue testing:

In the Community, Member States implement national residue control plans in all food producing animals according to Directive 96/23/EC. For horses in particular, 3000 animals were tested for the presence of pharmacologically active substances and contaminants in 2007.

Imports of equine meat in accordance with Council Decision 79/542/EEC and of equidae for slaughter in accordance with Council Directive 90/426/EEC are only authorised if equidae are included in the residue control plan established by the third country of origin and approved by the Commission according to Chapter II (4) of Annex IV to Directive 96/23/EC.