

15 April 2013

## Frequently asked questions on Phenylbutazone in horsemeat

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### 1. What is phenylbutazone?

Phenylbutazone – sometimes also referred to as “bute” – is a substance that falls into the class of drugs known as non steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are routinely used as painkillers in human and veterinary medicine. Phenylbutazone was introduced in 1949 as a human medicine for the treatment of rheumatoid arthritis and gout. These days it is used only under specialist supervision in patients who suffer from a severe form of arthritis where other treatments have not worked.

Phenylbutazone is used for the treatment of pain and fever in horses and dogs. In horses, some Member States permit its use for the management of chronic bone and joint problems e.g. arthritis, tendinitis in sport horses and horses kept as companion animals not destined for the food chain

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2. What is the situation regarding phenylbutazone in food in the EU?

Phenylbutazone is not allowed in the food chain and findings of this substance in horsemeat are the result of illegal entry into the food chain of carcasses of horses treated with the substance. According to EU legislation, treatment of horses with phenylbutazone must be recorded in their “horse passport”, resulting in the definitive exclusion of the animals from slaughter for human consumption.

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3. Why was phenylbutazone banned for use in food-producing animals?

EMA evaluated phenylbutazone in 1997 for the purpose of establishing maximum residue limits (MRLs) in food products of animal origin. The data available at that time did not allow a conclusion to be drawn on the level of phenylbutazone that could be considered safe in food of animal origin. As no MRL could be established, animals treated with phenylbutazone are not allowed to enter the food chain.

No new adequate data have become available since then and the recent risk assessment carried out by EFSA and EMA confirms that it is not possible to establish levels of residues of phenylbutazone that could be considered as safe in food of animal origin.

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4. What are the known toxic effects of phenylbutazone?

Phenylbutazone is toxic to bone marrow and exposure to this substance has been associated with aplastic anaemia, a potentially life-threatening blood disorder in which the body's bone marrow does not make enough new blood cells. If people are treated with phenylbutazone, aplastic anaemia is estimated to occur in a small number of sensitive individuals at a rate of approximately 1 in 30,000.

There are also uncertainties regarding the potential genotoxicity (the capacity to damage DNA of cells) and carcinogenicity of the substance.

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5. What is the likelihood of consumers being exposed to phenylbutazone in horsemeat?

Taking into account results of the monitoring of phenylbutazone in horsemeat over an 8-year period, including the reinforced testing plan carried out in March 2013, EFSA and EMA conclude that the likelihood of Europeans being exposed to phenylbutazone through the consumption of horsemeat (or beef products adulterated with horsemeat) is estimated to be low.

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6. What were EFSA and EMA asked to do by the European Commission?

EFSA and EMA were asked to carry out a joint risk assessment on the presence of residues of phenylbutazone in horse meat and provide advice on any potential risk to consumers. The agencies

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were requested to consider both the risk posed from direct consumption of horse meat and the risk from other products illegally adulterated with such food. EFSA and EMA were asked to make appropriate recommendations to further reduce the risk of phenylbutazone entering the food chain.

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7. What information did EFSA and EMA consider in their risk assessment of phenylbutazone?

EFSA and EMA investigated all possible safety concerns related to phenylbutazone as part of their joint risk assessment. In doing so, EFSA and EMA considered all available scientific evidence and data on phenylbutazone as well as information on consumption levels of horsemeat in the EU. Results from horsemeat tests made by Member States over an eight-year period, including the reinforced testing plan carried out in March 2013 were also utilised.

The agencies reviewed the 1997 assessment of phenylbutazone by EMA in light of current knowledge as well as any new relevant scientific evidence with regard to main issues of concern. These were identified as the rare blood disorder aplastic anaemia, genotoxicity and carcinogenicity. The new data available were however very limited. For the exposure assessment, information on consumption levels of horsemeat and beef-based products in the EU and residue monitoring data were used to form the basis for the risk estimation.

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8. What are the main conclusions of the joint statement?

EFSA and EMA conclude that the illegal presence of residues of phenylbutazone in horsemeat is of low concern for consumers due to the low likelihood of exposure and the overall low likelihood of toxic effects.

The joint assessment finds that, on the basis of available data, it is not possible to set safe levels for phenylbutazone in food products of animal origin. This reconfirms the conclusions of the previous evaluation carried out by EMA in 1997.

Therefore the use of phenylbutazone in the food chain should remain prohibited.

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9. What did the report conclude with regard to the potential risk for consumers?

The report concluded that the likelihood that an individual predisposed to aplastic anemia consume horsemeat contaminated with phenylbutazone and develop this condition is low –between 2 in a trillion and 1 in 100 million. This estimate takes into account the likelihood of consumers being exposed on any given day to phenylbutazone both from horsemeat itself and from beef-based products adulterated with horsemeat.

EFSA and EMA concluded that while genotoxicity of phenylbutazone could not be excluded, it was considered unlikely. The risk of carcinogenicity is also considered of very low concern given the estimated infrequency of consuming horsemeat containing residues of phenylbutazone (consumed as

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such or in beef-based products adulterated with horsemeat) and the estimated low levels of the drug to which consumers could be exposed through the diet. In estimating possible levels of phenylbutazone in foods, scientists used the highest concentration of the drug reported in the testing programme carried out by Member States.

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10. What recommendations did EFSA and EMA make to further reduce the risk of phenylbutazone entering the food chain?

The recommendations in the statement focus on strengthening traceability of horsemeat in the food chain across the European Union. The introduction of a consistent identification system to improve traceability of horses and other so-called solipeds would be beneficial. This includes strengthening the enforcement of the horse passport system.

EFSA and EMA call for improvements to the current methodology used to collect data on the presence of residues of veterinary medicines in live animals and food products of animal origin. EFSA previously made this proposal in its 2009 annual report on Veterinary Medicines Residues. EFSA and EMA recommend that harmonised control measures for sampling and detection of phenylbutazone be introduced throughout EU Member States.

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11. What is EFSA's role with regards to the management of issues such as the contamination of beef products with horsemeat?

In the EU food safety system, EFSA's role is to provide scientific advice regarding food and feed safety. EFSA does not have a remit regarding false labelling, food quality and traceability in the EU food chain, issues that are raised by the recent contamination of beef products with horsemeat. These issues and any risk management decisions arising from them fall under the responsibility of Member States and the European Commission. In such instances, EFSA can provide scientific assistance and advice on any food safety aspects to support EU risk managers in their decision making should this be required.

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12. What is EMA's contribution to this joint risk assessment regarding the public health implications of phenylbutazone in horsemeat?

The EMA's Committee for Medicinal Products for Veterinary Use (CVMP) is the scientific committee responsible for recommending maximum residue limits (MRLs) for active substances used in veterinary medicines. As such, it has a responsibility in relation to providing scientific advice on consumer safety concerns resulting from the use of veterinary medicines in food producing animals. EMA previously reviewed phenylbutazone and concluded that there were insufficient data to allow a recommendation for MRLs for the substance. The CVMP endorsed the joint statement from the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) on the presence of residues of phenylbutazone in horsemeat at its meeting from 9-11 April.

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