



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

ETHANOL

SUMMARY REPORT

1. Ethanol is used as an excipient (solvent, preservative) in human and veterinary medicinal products.
2. The acute effects on metabolic functions are apparent only after an ethanol dose of 0.1 g/kg, and effects on psychomotor functions have been found within the whole dose range 0.2-4 g/kg.
3. A daily intake of ethanol which causes chronic irreversible effects on the liver (cirrhosis) in adults is 0.5-3g/kg bw per day. Probably significant effects occur only at exposures exceeding 1 g/kg bw/day. The relation between dose and long term damage to other organs is essentially less known but it is reasonable to assume that the risk is less than for liver damage.
4. Ethanol consumption in pregnant females may cause mental deficiency and microcephaly in the foetus.
5. Tumours of the oral cavity, pharynx, larynx, oesophagus and liver have been linked to the consumption of alcoholic beverages in humans.
6. The total amounts of ethanol administered to food producing animals are very small (generally less than 6 g per adult animal). Furthermore, the metabolism of ethanol in humans is relatively constant with time at 120 mg/kg bw per hour. It is expected that the rate of metabolism in animals is in the same order of magnitude, i.e. about 60 g/500 kg horse per hour. The metabolism rate per hour is much higher than the total amount to be administered in the veterinary product itself.
7. Since the complete dosage administered to animals is very low, the administration of ethanol as an excipient in veterinary medicinal products to food producing animals does not result in any risk to the consumer. It is therefore appropriate to include ethanol into Annex II of Council Regulation (EEC) N° 2377/90 for all food producing species.