



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

ACETYLSALICYLIC ACID, SODIUM ACETYLSALICYLATE, ACETYLSALICYLIC ACID DL-LYSINE AND CARBASALATE CALCIUM (Extension to all food producing species)

SUMMARY REPORT (2)

1. Acetylsalicylic acid (2-(acetyloxy)benzoic acid; CAS Number 50-78-2) is an anti-inflammatory, antipyretic and analgesic agent. It is the standard to which all the other non-steroidal anti-inflammatory drugs (NSAIDs) are compared. Acetylsalicylic acid is used in veterinary medicine mainly as its sodium salt, which may be administered orally in the drinking water or feed to pigs, calves and chickens. Acetylsalicylic acid DL-lysine (DL-lysine mono[2-(acetyloxy)benzoate]; CAS Number 62952-06-1) is administered to cattle and pigs, usually by intravenous, subcutaneous or intramuscular injection. Carbasalate calcium (CAS No 5749-67-7, acetylsalicylic acid calcium-urea) is normally administered orally to pigs, calves and chickens, in the drinking water or in the milk replacer to calves. These substances, which were previously administered to other species including sheep, horses and other species of poultry, are mainly used for the treatment of inflammatory musculoskeletal disorders.

These substances are currently included in Annex II of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Acetylsalicylic acid	Bovine	Not for use in animals from which milk is produced for human consumption
	Porcine	
	Chicken	Not for use in animals from which eggs are produced for human consumption
Sodium acetylsalicylate	Bovine	Not for use in animals from which milk is produced for human consumption
	Porcine	
	Chicken	Not for use in animals from which eggs are produced for human consumption
Acetylsalicylic acid DL-lysine	Bovine	Not for use in animals from which milk is produced for human consumption
	Porcine	
	Chicken	Not for use in animals from which eggs are produced for human consumption

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Pharmacologically active substance(s)	Animal species	Other provisions
Carbasalate calcium	Bovine	Not for use in animals from which milk is produced for human consumption
	Porcine	
	Chicken	Not for use in animals from which eggs are produced for human consumption

2. Following concern that an insufficient number of medicinal products was available to treat diseases occurring in animals, and especially diseases occurring in minor animal species, the CVMP conducted a review of the risk assessment approach for the establishment of MRLs and adopted a Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMA/CVMP/187/00-FINAL). This Note for Guidance and also the Note for Guidance on the Establishment of Maximum Residue Limits for Minor Animal Species (EMA/CVMP/153a/97-FINAL) state that the existing Annex II entry for a major species should normally also refer to the corresponding minor species. The criteria for extension of Annex II entries to all food producing species were originally laid down in the Working Document: Criteria for inclusion of substances into Annex II of Council Regulation (EEC) No. 2377/90 and extension of Annex II classification to other species (III/5935*/94-EN). The Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMA/CVMP/187/00-FINAL) reiterated these criteria.
3. A request was submitted to the EMA, whether it would be possible to extend the existing entry in Annex II of Council Regulation (EEC) No. 2377/90 to all food producing species, in accordance with the above guidelines.
4. Acetylsalicylic acid and its salts have been widely used in both human and veterinary medicine. The only exception is fish for which the substances have no therapeutic value. Except for the lack of indications for fish, acetylsalicylic acid and its salts do not have a species specific pattern of use and would therefore satisfy the criterion stated in the Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMA/CVMP/187/00-FINAL) for the extension of Annex II entries to all food producing species.
5. For acetylsalicylic acid and its salts, residues depletion data had been provided for 3 major species, cattle, pigs and chickens, enabling the estimated consumer intake to be compared with the ADI (0.0083 mg/kg bw, equivalent to 0.5 mg/person). In addition, data on pharmacokinetics and metabolism were available for a range of species including dogs, cats, pigs, cattle, horses, goats, rabbits and chickens, demonstrating that after both oral and parenteral administration, elimination of acetylsalicylic acid and its derived salts was generally rapid, particularly in ruminants. Thus species specific data were available for a wide range of species.

Conclusions and recommendation

Having considered that:

- a pharmacological ADI of 0.0083 mg/kg bw (i.e. 0.5 mg/person) was previously established for acetylsalicylic acid,
- acetylsalicylic acid, sodium acetylsalicylate, acetylsalicylic acid DL-lysine and carbasalate calcium have already been included in Annex II of Council Regulation (EEC) No. 2377/90, as amended, for bovine, porcine and chicken species with the exception of animals producing milk or eggs for human consumption,
- the criteria regarding extension of Annex II entries, stated in the Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMEA/CVMP/187/00-FINAL), were considered to be applicable to these substances,
- no pharmacokinetic or metabolism data were available for fish and the substances have no therapeutic value in fish;

the Committee for Veterinary Medicinal Products recommends the inclusion of acetylsalicylic acid, sodium acetylsalicylate, acetylsalicylic acid DL-lysine and carbasalate calcium in Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Acetylsalicylic acid	All food producing species except fish	Not for use in animals from which milk or eggs are produced for human consumption
Sodium acetylsalicylate	All food producing species except fish	Not for use in animals from which milk or eggs are produced for human consumption
Acetylsalicylic acid DL-lysine	All food producing species except fish	Not for use in animals from which milk or eggs are produced for human consumption
Carbasalate calcium	All food producing species except fish	Not for use in animals from which milk or eggs are produced for human consumption