15 November 2010
EMA/CVMP/EWP/324712/2010
Committee for Medicinal Products for Veterinary Use (CVMP)

Overview of comments received on 'Guideline on veterinary medicinal products controlling varroa destructor parasitosis in bees' (EMEA/CVMP/EWP/459883/2008-CONSULTATION)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	Danish Beekeepers Association
2	

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1. General comments – overview

Stakeholder No.	General comment	Outcome
1	The vast majority of beekeepers provide beeswax-foundation for their bees based on recycled beeswax from old comb. Some hydrophobic veterinary medicinal products or their metabolites may contaminate the beeswax and lead to increasing levels by repeated recycles of beeswax from treated colonies. The accumulation is dependent on the stability of the compounds to the heat-treatment in the wax-melting process. The concentrations of such VMP's or their metabolites in the beeswax may approach toxic levels or levels where contamination of the honey is likely to occur. Furthermore may constant presence of the VMP in the hive accelerate the development of resistant varroa mites against such VMP's. In this way the long term efficacy and the target animal safety of the VMP may be compromised. We therefore suggest that the guideline should include studies to evaluate VMP's for such adverse properties. Problems with accumulation of VMP's in recycled beeswax were discussed at the EMA Workshop on medicines for bees, 14-15 December 2009 in London (EMA/28057/2010). Studies on accumulation in wax (without recycling) have been requested by the CVMP for the summary report on Amitraz (EMEA/MRL/572/99 and EMEA/MRL/187/97).	Indeed, some acaricides can lead to residues in honey. Honey always contains wax. Both water soluble and organic solvent soluble substances may end-up in honey. In relation to the potential contamination of honey with residues transferred from wax it should be noted that the MRL set for honey does not distinguish between residues incurred as a result of treatment and residues incurred as a result of transfer from wax. In addition, it is acknowledged that wax particles may be present in honey. For substances for which MRLs in honey have been established, compliance with the MRL therefore continues to ensure consumer safety. It is accepted however, that for a number of substances the CVMP has concluded that there is not a need to set an MRL in honey. These substances are not considered to represent a consumer safety concern because either their toxicity is low and consequently exposure, even at high levels, will not represent a risk for the consumer, or because it is accepted that their concentration in honey will always remain low (for example because they are non-lipophilic and non-accumulating). The transfer of residues of substances of this type from beeswax to honey is therefore also concluded not to represent a consumer safety concern. It should also be noted that data exists to show that the residue values in honey from contaminated honeycombs are about 1700 times lower than the residue concentrations in honeycomb wax[1]. Also, for transfer of residues of a variety of varroacides from beeswax to honey, the level of residues in the wax needs to be at 2 digit ppm levels (10-60 mg/kg) for concentrations in honey to appear at 0.6 to 36 µg/kg levels[2]. It is therefore considered that the potential for transfer of residues from wax to honey is limited and does not represent a

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	References: Wallner, Klaus: Varroacides and their residues in bee products Apidologie 30 (1999) 235-248 Varroacides and their residues in bee products Bogdanov, S., Kilchenmann, V., Imdorf, A.; Acaricide residues in some bee products, Journal of Apicultural Research, Federal Dairy Research Institute, Bee Department, Liebefeld, 3003 Bern, Switzerland	consumer safety concern. With respect to bees wax, it is common practice to recycle it. In this way residues may persist in wax over the years. The problem is not new and it is related to substances that are not water-soluble. As recycling is usually done by heating, the residue level of a substance may be reduced (by evaporation). There is no scientific information which indicates a risk of acaricide residues in bees wax, and no toxic effects in bees and/or resistance-induction in *Varroa*-mites have been identified, Rather than being related to residues in wax, such possible adverse effects seem to be related to inappropriate use of acaricides. Those levels that have been observed are usually too low to induce such effects. So the likelihood of residues, building-up to levels that are toxic for bees (brood) and/or select for resistance in mites is considered low. Moreover, bees and mites do not come into contact with wax in a way that it may lead to the aforementioned effects. Although it is possible to study the persistence of substances in wax in relation to recycling, the likelihood of finding toxic effects on bees and/or reduction of susceptibility in mites, due to residues in bees wax, is considered very low, taking into account all adverse effects that can affect bee colonies. Therefore no recommendation on studies addressing effects of residues in bees wax in relation to bee toxicity and/or induction of resistance in *Varroa*-mites is made. Long term studies on bees are limited in the kind of information they can provide on the risk due to wax residues. Furthermore, it may not be appropriate to ask for such studies in bees being MUMS species and experience

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		has shown that even long term studies would not be appropriate to identify such effects. Good beekeeping practices as well as appropriate use of acaricides is a major issue in reducing the presence of residues in bees wax. References: 1. Bogdanov S., Kilchenmann V., Imdorf A., 1997. Acaricide residues in beeswax and honey. Apiacta 32: 72-80 ATTACHED (Page 5, 2nd paragraph). The same results in: Bogdanov S., Kilchenmann V., Imdorf A. 1998. Acaricide residues in some bee products. J. Apic. Res. (37): 57–67. 2. Wallner, K. 1995. The use of varroacides and their influence on the quality of bee products. Am. Bee J. 135(12): 817-821.