

**RESPONSES TO A CONSULTATION ON TESTING FOR
OXYTETRACYCLINE (OTC) RESIDUES IN HONEY FOLLOWING
TREATMENT OF BEES FOR A EUROPEAN FOULBROOD (EFB)
OUTBREAK IN SCOTLAND**

1. The above consultation was issued 18th March 2010 and closed on 15th April 2010. The consultation was sent to interested parties as listed in Annex B of the consultation and to other government departments & agencies. England, Wales and Northern Ireland issued equivalent consultations.

2. The key proposals on which the consultation sought views were:
 - Q1 - Is the proposed testing regime satisfactory?
 - Q2 - Which suggested Action level is preferred?

3. The FSA is grateful to those stakeholders who responded and sets out in the table below responses in order of the group responding along with the FSA's responses to stakeholders' comments.

SUMMARY OF SUBSTANTIVE COMMENTS TO THE FSA CONSULTATION ON TESTING FOR OXYTETRACYCLINE (OTC) RESIDUES IN HONEY FOLLOWING TREATMENT OF BEES FOR A EUROPEAN FOULBROOD (EFB) OUTBREAK IN SCOTLAND

Respondent	Method of Response	Comment	Response
Bee Farmers' Association of the UK	Letter	Q1: Y Q2: Option 2 – 20ppb Bulk honey in store found to be above the level should be kept in store to allow OTC to degrade	Noted
British Beekeepers Association	Email	Q1: Y Q2: Option 2 - 20ppb	
British Honey Association	Email	Q1: Y Q2: Option 2 – 20ppb; level used by Community Reference Laboratory (CRL) and FERA for VMD National Statutory Scheme. Honey above the Action limit should be stored for a further period and re-tested	Noted
Flint & District Beekeepers Association	Email	Q1: Y Q2: Option 2 – but with lower detection level of 10ppb	
Food & Drink Federation	Email	No comments from members	
FERA (Food & Environment Research Agency)	Letter	General comment provided: VMD currently funding apiary experiments to assist in establishing MRLs. Laboratories testing honey should have ISO17025 accreditation and use methods validated according to Commission Decision 2002/657/EC. Setting an action level may be in breach of EU requirements and risk infringement proceedings.	Noted and will be taken into account in advice given.
Lochaber Beekeepers Association	Handwritten (scanned)	Q1: Y, probably adequate Q2: Option 2 – 20ppb	

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<p>Perth & Kinross Council (Trading Standards Service)</p>	<p>Email</p>	<p>Q1: N –</p> <p>The proposal requires the food business operators to provide samples and arrange for the analysis. There is a significant likelihood that honey from hives treated with OTC in 2009 will have elevated levels of OTC.</p> <p>In the light of the consequences arising as the result of unfavourable test results there would be concerns about the integrity of samples submitted by the beekeeper himself. To avoid the likelihood of fraudulent samples being submitted we would only support the sampling of honey from treated hives by an independent body.</p> <p>Clarification is required as to whether the sampling for OTC would only apply to honey from treated hives or would it be extended to honey from other sources, including imported honey? Would the agreed action level apply to imported honey as well as to Scottish honey?</p> <p>Q2: Option 3 – Not Detectable</p> <p>Although there is a provision in European legislation that in certain circumstances an authorisation to use non-approved veterinary medicinal products in food producing animals can be granted by a Member State the MRLs are set at EU level (not MS level) and are directly applicable in all Member States. The MRL for OTC has not been set and therefore MRL for OTC, other than nil, would be in breach of the European law. European law provides for equal consumer protection in all Member States and honey contaminated with OTC cannot be marketed in any member state including the UK.</p> <p>The use of veterinary medicines in food producing animals has an impact on human health. Even miniscule levels of OTC can disturb the balance of intestinal bacteria. Inappropriate exposure to antibiotics can lead to an increase in antimicrobial resistance in human medicines. This places a significant responsibility on food producers who use medicines to treat food producing animals.</p> <p>The contamination of honey with antibiotic residues may not be perceived as a food safety issue; nevertheless levels of OTC other than nil would not only be illegal but could also reflect unfavourably on the reputation of Scottish beekeepers. The rationale behind the withdrawal of Chinese honey in 2002, contaminated with antibiotics, was the need to maintain the confidence of consumers that honey is a pure natural product free from contamination. The same principle should be applied to Scottish honey!</p> <p>The opinions regarding use of antibiotics in bees and MRL in honey vary amongst specialists. However, there is no evidence that residue levels other than nil are safe.</p>	<p>Noted; FSA is working closely with Scottish Government to ensure correct sampling & VMD has increased its honey sampling in Scotland for 2010 which will be undertaken by SG bee inspectors. This consultation is specifically in response to the use of OTC to treat the EFB outbreak in Scotland.</p> <p>Noted; Consumers have the right to expect that any residues that occur in foods should not present a food safety risk & should be as low as practically possible; and the Agency has a responsibility to assess potential risk and take appropriate action. In this case, FSA toxicological and SG medical advice indicated that there would be no food safety concerns at the application levels used. This consultation aims to identify a proportionate approach to provide reassurance to consumers and the honey industry.</p>
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Rowse	Email	<p>Q1: Y</p> <p>Q2: Option 2 – 20ppb</p> <p>It would be sensible to permit a representative, composite sample to be drawn from a number of 300kg drums. Our usual batch size is 3000kg, but in the current circumstances, it might be prudent to operate to a maximum lot size of 1000kg</p>	Noted
Scottish Beekeepers Association	Letter	<p>Q1: Y</p> <p>We would accept the proposed testing regime with the following conditions; there must be assurances that the bulked honey comes only from spring or early summer honey of 2010 otherwise there are likely to be dilution effects. The first honey harvests from each apiary are at highest risk of breaching the prescribed limits but later harvests may also be at risk. Sampling from bulk containers will have to be organised carefully as there may be heterogeneity due to poor mixing.</p> <p>Any testing regime should remain in place for an extended period. Although OTC has a relatively short half-life there are indications that half-life when stored in honey comb, warm bulk honey and cool bulk honey can vary considerably. There are studies showing it is detectable even over 6 months from application. Even when OTC is applied only to some hives in an apiary it has been shown to appear in other (non-treated hives) presumably from drifting foragers and so can be more persistent within apiaries.</p> <p>We believe that it is reasonable to allow honey which has OTC levels above the agreed limit a period of time to allow further degradation and then to be submitted for re-testing. Should contamination still remain above those levels then it should not be allowed to enter the food chain.</p> <p>Q2: Option 3 - Not Detectable</p> <p>We believe the preferred is option No. 3: i.e. below the limit of reliable detection at 10 µg/kg. Although the levels mentioned in the consultation document of 25µg/kg and 20µg/kg are unlikely to pose a serious problem to human health, Scottish honey could be rejected by EU countries for the reasons given above. So until the EU agrees on and sets an MRL for OTC in honey we would prefer this option.</p> <p>There is a Belgian study which has looked at locally produced honey and compared it with imported honey for various antibiotic residues. The results showed that 30-47% of imported samples were significantly contaminated with antibiotic residues. We do not wish Scottish honey to be included in these figures and hope this scenario can be avoided by rapid resolution of this European Foulbrood outbreak.</p>	<p>Noted and will be taken into account in advice given</p> <p>Noted</p>
Ulster Beekeepers Association	Letter	<p>Q1: The testing regime needs to be clearly specified, targeted on apiaries with treated colonies & less reliant on bulked up samples submitted by FBO's or constrained unduly by costs of sampling and testing.</p> <p>Q2: Option 3 – Not Detectable</p>	Noted

