Divergent opinion on MRL of "Purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)"

Hops have been cultivated and used by humans for hundreds of years and are currently used for flavouring purposes as well as in herbal medicinal products, where they are considered to be non-toxic and safe with no significant adverse effects. However experimental toxicological data on hop preparations are rather limited and incomplete.

Having considered that:

- No geno-toxic data are available for purified semi-solid extract of *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)
- No pharmacokinetic data are available for purified semi-solid extract of *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts) to demonstrate bioavailability
- No ADI can be established for purified semi-solid extract of *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts) as appropriate data are not available;
- Limited residue data indicate that intake of residues of purified semi-solid extract of *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts) resulting from its use in honey production will result in residue concentrations between LOD (0,4 ug/g) and LOQ (2,76 ug/g) of the analytical method for lupulone.
- The standard food basket includes a portion of 20g for the daily intake of honey. Assuming a concentration of 2.76 mg/kg beta acids in honey, the worst case intake of beta acids would be 55.2 µg/person.
- In the USA, where hop beta acids have GRAS status, it has been estimated that average daily intake of beta acids from beer and processed foods is 340 µg/person.
- In EU hop beta acids is NOT considered part of the normal diet. The beta acid content of beers is variable but does not generally exceed 1.0 mg/l. A single small (250 ml) beer may therefore lead to a consumer ingesting 250 µg of beta acids.
- Based on the US figures and the content of beta acids in beer it can be concluded that consumer intake of hop beta acids from honey produced in hives treated with potassium beta resins may represent one six to one fourth of the overall consumer intake of beta acids. This is not a negligible amount and absence of toxicological data can therefore not be accepted.
- In addition to hop beta acids the extract also contain 20-30% of 'other resins'. These have not be identified or toxicologically characterised either.
- No residue data are available demonstrating the concentration of "other resins" in honey following treatment of hives with potassium beta resin.

In conclusion, there are too many missing links in this application and therefore it is not scientifically acceptable to put "Purified semi-solid extract of *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)" in annex 1 with a status of no MRL is required.

Signature on file

Christian Friis London, 7 May 2015