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European Federation of Honey Packers and Distributors

Antibiotic Residues in Honey

The situation for the Trade and Industry

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Main concern of Trade and Industry

- Antibiotic Residues are found in honey
- Antibiotics in beekeeping are not only used in Third countries
- Antibiotics are also used in EU member states !

Reasons for use of Antibiotics

- Beekeepers fear loosing beehives
- Main indication for use of antibiotics are American and European Foulbrood

Most often Antibiotics used in beekeeping

- Streptomycine
- Sulfonamides
- Tetra- and Oxytetracyclines
- Tylosin
- Macrolides

Availability

- Third Countries (some)
  - Some products are authorized
  - MRLs are established for some substances
  - Use of some antibiotics is legal
- EU
  - No products authorized
  - No MRLs established
  - Use of antibiotics is forbidden

Problems

- Official “zero tolerance” policy of the EU
- Number of authorized medicine remains limited
- Beekeepers use no adequate medicine
- Necessity to fix control methods
- Necessity to fix detection limits
- Different and changing analysis methods
- Sampling methods not established . . .
- NO harmonised system in the EU member states

Legalization Process (in general)

- Application to EMEA
  - Safety dossier
  - Residue data
  - Toxicity studies

→ aiming to establish ADI

But
Assessment in Honey is complex

- Once treatment is done, residues remain in honey
- No withdrawal period from treatment to harvest of honey
- Monitoring or exposure data can be taken into consideration

MRLs for Honey

- Main antibiotic substances found in honey have MRLs for other species
- ADI for those substances is known
- = extension of the MRLs for bees/honey required

Marketing authorization for products

- Bees/honey is considered as minor species
- Certain requirements are eased for small to medium sized companies
- Market is unknown, maybe limited
- Limited interest of pharmaceutical companies to place products

Concerns

- Antibiotics may not be helpful
- Other options could be considered
- Resistance development may limit the use of antibiotics for animals and humans (this applies to all species)
- Residues in honey spoil the image of the product

FEEDMs' trial on Oxytetracycline

- Pfizer in cooperation of BHIPA applied for Oxytetracyclin in 2005
- CVMP recommends MRL of 25µg/kg the19th April 2006 for Anex I of 2377/90
- EU Commission complains that ADI of Oxytetracycline is already exceeded and asked for revision
- CVMP reconfirms 25µg/kg on 19th Feb 2007
- Since than involved DGs could not agree on whether including Oxytetracyclin for honey in Anex I or III of 2377/90
- _____
- No harm for human consumers but still "zero tolerance"

New attempt

- COPA/COGECA, FEEDM, IHC
- Parties involved ask the Commission for MRLs
  - Flourquinolones 0,005 ppm
  - Macrolides 0,020 ppm
  - Streptomycins 0,010 ppm
  - Sulphonamides 0,010 ppm
  - Tetracyclines 0,010 ppm

Low limits to be fixed for legal security (Sep 2009)

The Commissions' reply

- DG Enterprise
  - Letter submitted to DG Sanco for RPAs
  - Request on MRLs may be submitted to EMEA
    - Article 9(1)b of EC No 470/2009 and Art. 11 of 2001/82
- DG Sanco
  - Commission may establish RPAs
  - Alternative are MRLs,
    - according to 470/2009, arts 5 (EMEA) and 6(3)
  - DG Enterprise is responsible
- EMEA
  - Only a member state or the Commission may ask for MRL
    - according to Art 9 of EC 470/2009
  - DG Sanco is responsible for RPAs

Which way has to be taken?