Antibiotics in Honey (CSE Study)

We are here because…

- **Antibiotics in our food are now a global health concern:**
  - Adverse health impacts
  - Proliferating resistance in bacteria, thereby making antibacterial treatment ineffective

- **WHO says antibiotic resistance is "one of the three greatest threats to human health"**

Why antibiotics …

- **Antibiotics in India are widely used in Food Animals:**
  - As ‘growth promoters’
  - To prevent infections
  - To treat infections

- **However, there is no data on this usage!** Neither there is any regulatory provision regarding the use of antibiotics in Livestock. Only aquaculture has some rules on antibiotics, possibly far from satisfactory

- **WHO recognises irrational use of antibiotics in animal husbandry as one of the six key reasons of development of antibiotic resistance**

Why CSE tested for antibiotics in honey!

- **To expose the regulatory 'black hole' that got created due to**
  - Setting up of an elaborate system of monitoring antibiotics in '**honey for exports**' by Export Inspection Council (EIC), when European Union (EU) banned Indian honey with antibiotic residues couple of years ago
  - While honey sold in domestic market **was left unregulated** for presence of antibiotic residues

- By now, EU rejection of Indian Shrimp had already triggered EIC
  - 50 shrimp consignments were rejected in 2009 and 30 in 2008
  - In 2002, three consignments were destructed after Chloramphenicol was detected

How honey is regulated Internationally?

- **Codex:** Standard (Codex Stan 12- 1981 Rev 1 1987 Rev2 2001) defines honey as a 'natural product' and lays down standards on quality. **However, no standards for antibiotics**

- **EU:** Defined honey under the Council Directive 2001/110/EC as a 'natural product'. **Standards for antibiotics is not listed** which means that the use of antibiotics in honeybees **not permitted** and therefore considered **"unauthorised substance"**.
  - However, had set **Reference Points for Action (RPAs) for few antibiotics for imported honey** at the level of detection of the testing instruments

How honey is regulated Internationally?

- **USA:** Regulated by the Food and Drug Administration, but there were no limits set for antibiotics in honey.

- **Australia:** Australia had set standard for only Oxytetracycline in honey at 300 ppb. For others, no standards.

- **'No standards'** meant that antibiotic in honey is an **"unauthorised substance"** and therefore not permitted. **A reason why honey consignments from India were rejected after it was found contaminated with high amount of antibiotics**

So…

What about our regulators?

What about the honey we eat?...

Indian regulations

- Import and domestic consumption is managed by **FSSAI**
  - Erstwhile **PFA Act and Rules,** which were mandatory, defined honey as a **'natural product'**
  - Has standards for **'quality'** and only NOW after CSE's study, regulations on antibiotics in honey seem to be shaping up

- Voluntary **Bureau of Indian Standards (BIS)** norm for **Extracted Honey (IS 4941:1994)**. Brands with ISI mark were to meet this standard on quality. But **no antibiotic standards**

- **Honey Grading and Marking Rules, 2008** under the Agricultural Produce (Grading and Marking) Act, 1937 (AGMARK); implemented by Ministry of agriculture

Indian regulations (only for exports)!

- Department of Commerce, through **EIC** monitored the quality of products exported from India

- EIC setup a **Residue Monitoring Plan (RMP)** to monitor the level of antibiotics, heavy metals and pesticides contamination in honey meant for exports

- And **'Level of Action' (standards)** for antibiotics in exported honey. Sample found to be containing antibiotics beyond the standard is deemed non-compliant and rejected for exports

Regulatory ‘black hole’!

Since no standards, honey was not monitored, tested or checked by our regulators. But this was not the case for honey destined to be exported.

So CSE tested…

- **12 branded honey sample – 10 domestic brands and two imported brands**
  - Dabur Honey of Dabur India Ltd, which had over 75% of the market share
  - Baidyanath Wild Flower Honey of Shree Baidyanath Ayurved Bhavan Pvt Ltd, which had 10% market share
  - Himalaya Forest Honey of Himalaya Drug Company
  - Patanjali Pure Honey of Patanjali Ayurved Ltd

  - **Six lesser known brands** such as Khadi Honey, Mehsons Honey, Gold Honey, Umang Honey, Himflora Gold, Hitkari Honey

So CSE tested…

- **Two imported brands**
  - Capilano Pure & Natural Honey of Capilano Honey Ltd, Australia, a market leader in Australia
  - Nectaflor Natural Blossom Honey of Narimpex AG, Switzerland

Methodology used

- The samples analysed in triplicate using High Performance Liquid Chromatography (HPLC) with Diode Array Detector (DAD) and Fluorescence Detector (FLD)

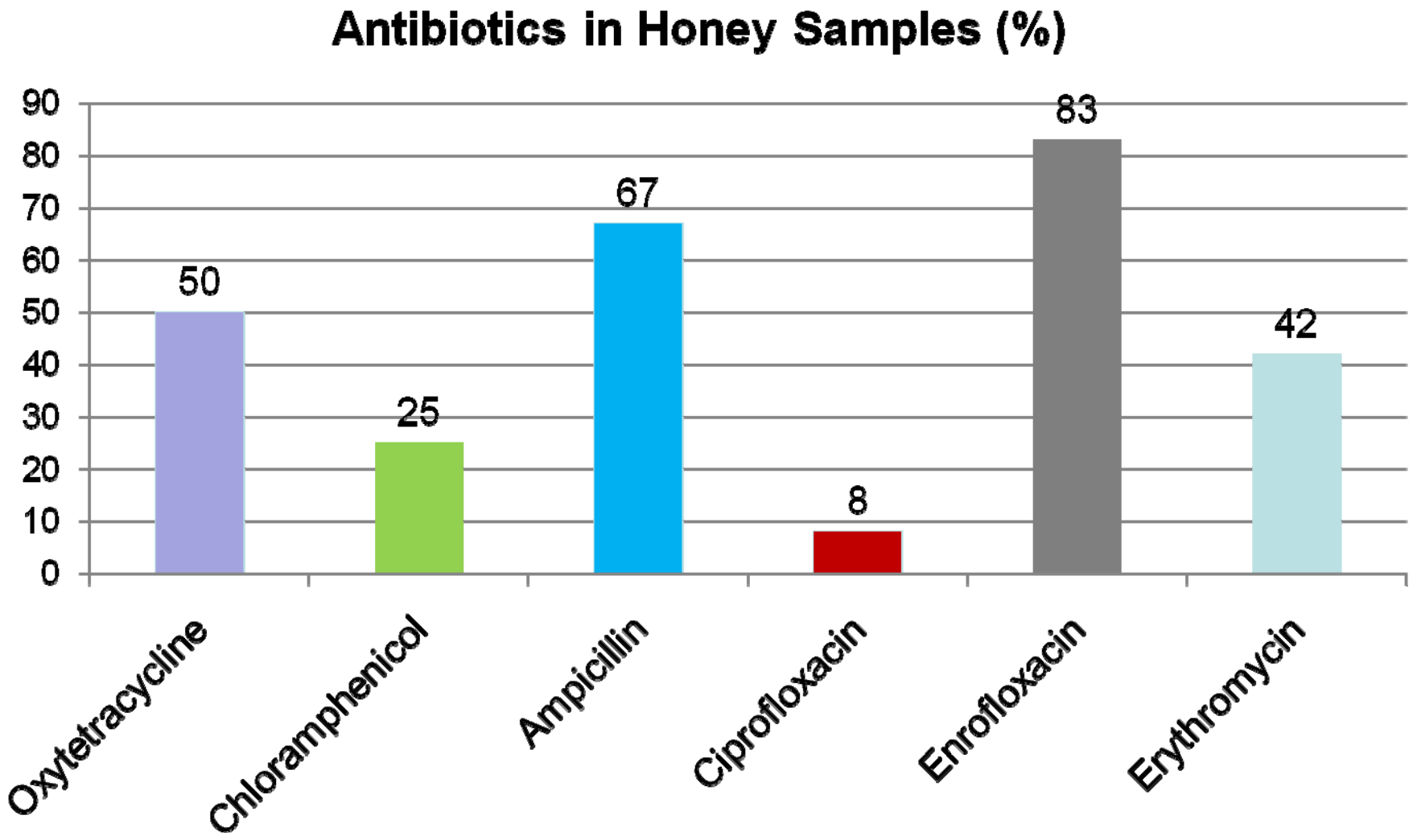
- Internationally accepted published methods were used for analysis and validated by CSE's Pollution Monitoring Laboratory

- The results were confirmed by spiking

Key findings

- Multiple antibiotics (2 to 5) in high amounts were found in **11 out of the 12 samples**
- All 11 samples failed the EIC standards for honey to be exported
- The two imported honey samples were also highly contaminated with antibiotics. **Both would have failed their own domestic standards**
- The fact that more than one antibiotic was found in the samples indicates most are blended honey from multiple sources. **So one does not know from where honey has been sourced**

Antibiotics



How much?..and the mix

Antibiotic	Common Usage	Quantity (µg/kg)	Quantity to EIC Standard
Oxytetracycline	**Bacterial foul brood disease in bees**	**27.1-250.4**	**3-25 times higher** than the 10 µg/kg
Chloramphenicol	Banned in food-producing animals in many countries	3.6-4.4	**12-15 times higher** than the 0.3 µg/kg
Ampicillin	Veterinary medicine; not recommended on honeybees	10.1-614.2	No standard for honey; illegally present
Enrofloxacin	As a growth promoter in cattle; now being used in beekeeping	10.9-144.8	No standard; illegally present
Ciprofloxacin	In poultry farming	19.9	No standard; illegally present
Erythromycin	For poultry; now reportedly being used in beekeeping	69.7-280.3	No standard; illegally present

In domestic brands…

Brand	Antibiotic (µg/kg)	Comparison with EIC Standard
Dabur Honey	• Oxytetracycline (91.3) • Enrofloxacin (88.7) • Ampicillin (26.6)	**Level of Oxytetracycline is 9 times**
Himalaya Forest Honey	• Erythromycin (69.7) • Enrofloxacin (63.8) • Ampicillin (23.8)	Sample non-compliant, as there are no standards
Mehsuns Pure Honey	• Erythromycin (85) • Enrofloxacin (53.5)	Sample non-compliant
Himflora Gold Honey	• Enrofloxacin (37.7) • Ampicillin (35.5)	Sample non-compliant
Patanjali Pure Honey	• Erythromycin (186) • Enrofloxacin (75.17) • Ampicillin (30.5) • Oxytetracycline (27.2)	**Oxytetracycline is almost 3 times**
Biadyanath Wild Flower Honey	• Ciprofloxacin (19.9) • Ampicillin (25.2)	Sample non-compliant, as there are no standards

…also in imported brands (abundantly)

Brand	Antibiotic Present (µg/kg)	Comparison with EIC Standard
Khadi Honey	• Oxytetracycline (250.4) • Enrofloxacin (10.9) • Ampicillin (10.1)	**Oxytetracycline is 25 times, the highest among all tested brands**
Gold Honey	• Erythromycin (231.3) • Oxytetracycline (57.7) • Enrofloxacin (34.3) • Ampicillin (4.4)	Oxytetracycline is ~6 times; **Chloramphenicol is the highest among all tested brands**
Hitkari Honey	No antibiotics detected	Not applicable
Umang Honey	• Ampicillin (208.1) • Enrofloxacin (122.1)	Sample not compliant with EIC standards
Capilano Pure and Natural Honey	• Oxytetracycline (150.8) • Enrofloxacin (144.8) • Chloramphenicol (3.6)	**Oxytetracycline is 15 times the EIC standard**, but within Australian standard; Chloramphenicol which is banned in Australia is ~12 times the EIC standard
Nectaflor Natural Honey	• Ampicillin (614.2) • Erythromycin (280.3) • Oxytetracycline (112.0) • Enrofloxacin (56.1) • Chloramphenicol (3.6)	**Oxytetracycline is 11 times the EIC standard;** Chloramphenicol which is banned in EU, is 12 times over the EIC standard

What followed the CSE study

- **FSSAI** issued an advisory in **Sept 2010:**
  - No antibiotic and pesticide residues are allowed in honey
  - It added that *"with regard to antibiotics in honey, the safety standards in India are similar to the rules in the European Union, Codex Alimentarius and the USA where they are completely prohibited"*
- **August 2011**, FSSAI's scientific panel:
- Noted enough evidence of antibiotics and a need for a well designed, uniform risk assessment study on consumption patterns of honey in children and the elderly
- Mentioned that except certain antibiotics of tetracycline class, others are contaminants
- Cautioned fixing of MRLs to avoid providing an escape route

What followed the CSE study

- **Oct 2011**, FSSAI's panel:
  - Decided to follow EU norms for antibiotic residues and set LOQs (Limits of Quantifications) for those which were not included under the EU norms
- **Dec 2011**, FSSAI's panel recommended a list of antibiotics with their LOQs
- **June 2012, FSSAI** approved recommendations of its scientific panel, which says antibiotics should not be used at any stage of honey production

Meanwhile…

- Government of India directed the BIS to analyze the CSE study
  - The 32-member technical committee of the BIS agreed that clause 5.4 of IS 4941:1994 ‘Extracted Honey – Specification (second revision)’ needs to be revisited and that **no antibiotics should be tolerated in honey**

- **Health ministry sets timeframe** to keep away animals such as dairy cattle, treated with antibiotics out of human food chain. Antibiotics that are used for therapeutic purposes in animals, should be **labelled with the withdrawal period**

Meanwhile…

- **National Policy on Containment of Antimicrobial Resistance** formulated by Union ministry of health and family welfare in 2011:
  - Acknowledges that antibiotics are used as growth promoters
  - Points out a need to regulate the use of antibiotics in poultry, other animals and a requisite labeling requirement
  - Calls for a ban on the use of antibiotics in livestock for non-therapeutic uses

It remains to be seen…

- If (at all) regulators would be able to catch up with the intensity of industry promoting this
- How many studies such as the one on Honey are required!

BY THE WAY

In 2003, FAO, the World Organization for Animal Health and WHO concluded *"there is clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of antimicrobials. These consequences include infections that would not have otherwise occurred, increased frequency of treatment failures, and increased severity of infections".*