Centre for Science and Environment
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Antibiotics in honey

Factsheet 2: Regulations: not working to regulate contaminants

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Rules regarding honey
The European Union (EU) has, in the past 10 years, rejected Indian honey many times after it was found contaminated with antibiotics and lead and had an absence of traceability[1]. With the ban came the directive of the Export Inspection Council (EIC) issuing orders to the exporters and packers, the drug controller of India and the national bee board to ensure that EU demands were met[2]. The country even set standards – called Level of Action – for the export of antibiotics.

So while we are ready to mend our ways to meet demands for others, we turn a blind eye to what comes to India and what Indians eat. The CSE lab study reveals that two imported brands -- one from Australia (*Capilano Pure & Natural Honey of Capilano Honey Ltd)* and the other from Switzerland *(Nectaflor Natural Blossom Honey of Narimpex AG)* have high doses of antibiotics present in the honey. But India does not have any regulations to check what is coming into the country and what we are eating. Clearly, no one in India is bothered about what we are eating.

Enlisted below are some of ***international and Indian regulations***:

- **Codex**: Honey is an internationally traded commodity. Codex has standards for the quality of honey which is traded. It defines honey as that produced by *Apis mellifera* (European bee) and has no standards for antibiotics.

- **European Union**: The EU regulates honey under the Council Directive 2001/110/EC. The standard for antibiotics in food (referred to as Maximum Residue Limits or MRLs) is listed in Regulation (EU) No 37/2010 -- it stipulates that each antibiotic must have an MRL before it can be used on a food-producing species. ***But there are no MRLs for antibiotics in honey, which means EU does not allow the use of antibiotics for treatment of honeybees.*** But EU member states do import honey and for regulating residues of antibiotics in imported honey, the bloc has set RPAs, or 'Reference Points for Action'. RPAs are residue concentrations which are technically feasible to detect by food control labs. When antibiotics are detected by a laboratory, the member state is obliged

[1] See final report of European Commission's Food and Veterinary Office (FVO) report on evaluation of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.
[2] See presentation by the Export Inspection Council at an internal meeting at the Union ministry of commerce on August 25, 2010.

to reject the consignment. Till date, RPAs have been established in honey for substances such as chloramphenicol and nitrofurans. **EU has also set a provisional MRL of 25 parts per billion (ppb) for oxytetracycline in honey**. EU considers the use of substances like formic acid, oxalic acid and lactic acid safe.

- **USA:** MRLs for antibiotics in food are set by the US Food and Drug Administration (USFDA), and listed in Title 21, Part 556 (21 CFR 556)[3]. **There are no limits for antibiotics in honey.**

  *(*According to regulators in the EU and the US, antibiotics in honey are 'unauthorized' and therefore, 'illegal', unless there is a standard regulating their levels. This is the pretext on which EU banned Indian honey from entering its shores.*)*

- **Australia/New Zealand:** The Food Standards Code (Standard 2.8.2) defines honey and sets compositional requirements for the product. Standard 1.4.2 lists the maximum permissible limits for agricultural and veterinary chemical residues present in food. Schedule 1 lists all of the agricultural and veterinary chemical limits in particular foods. If a maximum residue limit for an agricultural or veterinary chemical in a food is not listed in Schedule 1, there must be no detectable residues of that agricultural or veterinary chemical in that food. Commodity and commodity groups which are referred to in this Standard are listed in Schedule 4 which specifies the part of the commodity to which the maximum or extraneous residue limit refers and honey is listed under Animal Food Commodity. **Australia has set MRL for only oxytetracycline in honey at 300 ppb. Other antibiotics in honey are not allowed.**

- **Canada:** Canada's Veterinary Drugs Directorate (VDD), in agreement with the Canadian Food Inspection Agency (CFIA), has amended the joint Policy on Administrative Maximum Residue Limits/Maximum Residue Limits (AMRLs/MRLs) for Veterinary Drugs in Food Products to include Working Residue Levels (WRLs) for antimicrobials used in honey. WRLs are recommended levels for drug residues in honey below which there is considered to be no undue risk to human health. The WRLs for honey have been derived by extrapolating lowest established AMRL/MRL values of antimicrobials that are approved for use in other food-producing animals. **Chloramphenicol and nitrofuran antibiotics are banned in Canada. AMRL for oxytetracycline is fixed at 300 ppb and WRL of erythromycin is 30 ppb.[4]**

- **India:** Honey is currently regulated under three legislations[5]:
  • ***Prevention of Food Adulteration (PFA) Rules, 1955***, a mandatory standard, implemented by the Food Safety and Standards Authority.
  • The voluntary ***Bureau of Indian Standards (BIS)*** norm for extracted honey under IS4941:1994. Brands wishing to obtain the ISI mark will have to follow it.

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[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=556
[4] The Veterinary Drugs Directorate of Health Canada at http://www.hc-sc.gc.ca/vetdrugs-medsvet/mrl_oxytetracyclineletter_e.html
[5] CSE lab study

• Honey Grading and Marking Rules, 2008 under the **Agricultural Produce (Grading and Marking) Act, 1937 (AGMARK),** implemented by the Union ministry of agriculture.

All three define honey as a “natural product” and lay down standards for its composition and quality (like sucrose content, total reducing sugars and moisture content) -- **but there are no standards for antibiotics in honey.**

Indian regulators believe if there are no standards, they can’t regulate. But this perception undergoes a sea change when it comes to honey for export. For this, an elaborate system of monitoring (called Residue Monitoring Plan or RMP) has been put in place, and the Exports Inspection Council (EIC), under the Union ministry of commerce and industries, has been entrusted with the task of checking exports.

EIC standards: The EIC has set antibiotic standards for honey which is exported. This is referred to as ‘Level of Action (LOA)’ -- the limit beyond which a sample is deemed non-compliant and rejected for exports. These LOAs have been set for antibiotics; for instance, the LOAs are set for oxytetracycline (10 ppb) and chloramphenicol (0.3 ppb).

These rules are not applicable to honey sold domestically or as checks for imported honey.
