

CENTRE FOR SCIENCE AND ENVIRONMENT

MAIN OFFICE: 41, Tughlakabad Institutional Area, New Delhi-110 062 INDIA

Tel: +91 (011) 4061 6000, 2995 5124, 2995 6110 Fax: +91 (011) 2995 5879 Email: cse@cseindia.org Website: www.cseindia.org

BRANCH OFFICE: Core 6A, Fourth Floor, India Habitat Centre, Lodhi Road, New Delhi-110 003

Tel: +91 (011) 2464 5334, 2464 5335



December 13, 2017

LEAVES
OF
IMPORTANT
SURVIVAL
TREES
IN
INDIA —
MAHUA,
KHEJDI,
ALDER,
PALMYRA
AND
OAK

Shri Pawan Kumar Agarwal
Chief Executive Officer
Food Safety and Standards Authority of India
3rd Floor, Food and Drug Administration Bhawan
Kotla Road
New Delhi 110002

Subject: CSE recommendations on Draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulation-2017 related to tolerance limit of antibiotics and pharmacology active substances.

Dear Shri Pawan Kumar Agarwal ji,

This has reference to the **Draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulation-2017 related to tolerance limit of antibiotics and pharmacology active substances—uploaded on 15.11.2017.**

At the outset, we welcome the FSSAI's step of setting tolerance limit of antibiotics in food from animals, in view of its significance in addressing antimicrobial resistance (AMR), a growing public health threat.

We, at the Centre for Science and Environment (CSE) have been working on the issue of antibiotic misuse in food-animal production for nearly a decade and have been advocating for antibiotic residue standards for food animal products such as milk, meat and eggs. In the past, our studies on honey, poultry and aquaculture highlighted rampant misuse of antibiotics (including those which are critically important for humans) and presence of antibiotic residues in food from animals. As you would know, food from animals is a key route for transfer of antibiotic residues and resistant bacteria to humans which is strongly associated with emergence of AMR. In addition, antibiotic misuse in food animal production settings is also responsible for environmental spread of AMR. In this regard, the proposed draft notification holds significant relevance. **While FSSAI's step is in the right direction, but the draft needs to be strengthened. We have identified certain gaps and based on those recommend necessary modifications as below.** The same are also provided in the desired format.

- **Modify the list of antibiotics which are prohibited for use in any unit processing sea foods including shrimps, prawns or any other variety of fish and fishery products.** The proposed draft omits nalidixic acid, neomycin and fluoroquinolones, which were a part of the earlier version of Food Safety and Standards (Contaminants, Toxins and Residues) Regulations 2011. Since these are critically important antibiotics (CIAs) for humans as per the 5th Revision of the WHO list of CIA (2017), the FSSAI regulations must help limit their use in food animal production. Further, fluoroquinolones are classified as Highest Priority CIAs based on their significance to humans and are needed to be preserved. The list should therefore be modified to retain these antibiotics.

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- **The basis of segregation of antibiotics as per human use and animal use as well as selection of specific antibiotics needs to be modified and strengthened.**
 - **It must be ensured that tolerance limits are set only for antibiotics which are approved** by the Central Drug Standards Control Organization (CDSCO) for use in veterinary sector. It should not be only about use, which could be unapproved and illegal. Further, among those which are approved, the tolerance limits – in view of globally adopted approaches to address AMR from food animal production – must discourage use of CIAs for humans. In particular, prohibit use of highest priority CIAs.
 - The tolerance limits should be based on a consolidated and complete list of antibiotics approved by the CDSCO and all state drug departments. At present, in absence of such consolidated list (at least in public domain), it is difficult to ascertain the basis for segregation and selection of the antibiotics which have been enlisted.
- **Highest priority CIAs such as Erythromycin, Ceftiofur, Colistin Sulphate should not be allowed for use in food animals.** Preserving highest priority CIAs for humans is a key approach to limit the impact of AMR from food animal sector. Antibiotic residue standards must be suited to discourage their use. Their presence should be detected at Limit of Detection (LOD) to discourage use. Moreover, the list of antibiotics that are exclusively used in animals needs to be corrected. For example, colistin sulphate is used in humans as a last-resort antibiotic. The WHO Model List of Essential Medicines also placed colistin as “reserve group antibiotics”.
- **Surveillance of unapproved antibiotic use must be incorporated in the draft. The draft must clarify that antibiotics other than those with tolerance limit mentioned are not allowed and their unlawful presence would be detected at LoD.** Apart from antibiotics which have been listed, many more different antibiotics are used for food animal rearing such as in poultry and dairy, many of which are also CIAs. In fact the current list is more far than closer to the ground realities of antibiotic use. Apart from checking for residues of antibiotics listed, the FSSAI should have a surveillance framework to detect residues of unapproved antibiotics and the draft notification must include that. In order to detect such unlawful use of unapproved antibiotics, LoD should be used as a stringent and sufficient criterion.
- **The draft should be modified to restrict use of antibiotics such as chloramphenicol, furazolidone and carbadox, for which no MRLs (maximum residue limits) are given in relevant Codex and European Union (EU) standards.** According to the Codex, there is no safe level of residues of these drugs or their metabolites in food that represents an acceptable risk to consumers. Hence these should be avoided for use in food and food animals. The EU Commission Regulation (no. 37/2010) also prohibits use of chloramphenicol and furazolidone and does not provide MRLs for these. By providing tolerance limits, FSSAI is allowing their use. The proposed draft should therefore be modified to remove these antibiotics.



- **The proposed draft must clarify if “All edible animal tissue” includes fish or not.** It will have different implications based on what is intended, which further needs to be reviewed by stakeholders after it is clarified.
- **In case of eggs, tolerance limits mentioned for only few antibiotics.** Several antibiotics are used in layer birds and it is important to set standards for those. It must be clarified, if the draft considers eggs as part of ‘All edible animal tissue’. If not, tolerance limits for several other antibiotics in eggs must be provided.
- **The draft should discourage growth promoter use of antibiotics.** Antibiotics such as salinomycin, sulphadiazine, sulphathiazole sodium, amprolium hydrochloride, clopidol, flavomycin, sulphadimidine sodium, sulphaquinoxaline, tyvalosin tartarate and virginiamycin (listed in Table 1 and 2) are not part of Codex and EU MRL standards. Many of these are used as growth promoters and are not allowed in the EU. Therefore, it would be important to exclude them from the list to discourage their use.

We hope that the FSSAI incorporates our recommendations while finalising the draft.

Please let us know if there are any queries. We would be happy to meet and present if required.

With my best wishes,

Yours cordially,

Chandra Bhushan
Deputy Director General

Enclosed: CSE recommendations on Draft Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulation-2017 related to tolerance limit of antibiotics and pharmacology active substances **(in desired format)**

