# 04 REGULATORY LANDSCAPE IN INDIA

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There is no effective integrated policy to control the use of antibiotics in food-producing animals with a viewpoint of containing antibiotic resistance. While the regulatory measures adopted by certain countries such as Sweden and Denmark date back to 1980s and 1990s respectively, the state of regulatory landscape in India is far behind. There are certain sporadic provisions which are linked to the antibiotic resistance (ABR) but do not directly target it. Most of them are advisory in nature or have not made much progress (see Table 1). Broadly, the current situation and the regulatory gaps can be summarized as:

**Absence of a national-level integrated surveillance data on antibiotic resistance**

There is no national-level integrated surveillance data on antibiotic resistance in animals, humans and food chain. India was one of the 14 countries which could not submit surveillance data sought by World Health Organisation (WHO) for its global resistance report in 2013-14.[1] Such data is maintained only in few dedicated programs such as for tuberculosis. Otherwise, limited progress is achieved under the National programme on containment of antimicrobial resistance (2012-17), which plans to develop a national level data on ABR in humans.[2,3] As of today, it is limited to agreements with only 10 laboratories in eight states of India while the five year plan aims to have a network of 30 laboratories to measure resistance in select bacteria such as *Klebsiella pneumoniae, Escherichia coli, S. aureus* and *Entercocci* to start with. There is no national-level information on resistance in food producing animals and foods in public domain. The 2011 National Policy on containment of antimicrobial resistance does not focus on antibiotic resistance emanating from food-producing animals.[4]

**No country-wide information on volume of antibiotics used in food-producing animals and human**

Along with the data on resistance, information on the nature of antibiotic consumption is considered instrumental to frame policies aimed at containing antibiotic resistance. There is no country-wide data in the public domain to suggest the total volume of antibiotic used in food-producing animals including chicken. The situation is similar for a national-level assessment of human antibiotic consumption.

**Rampant use of antibiotic growth promoters. Feed additive antibiotics are largely unregulated**

Unlike member countries of the European Union (EU), there is no prohibition to the use of antibiotic growth promoters (AGPs) in India. In practice, AGPs are extensively used as feed supplements in intensive farm practices of the poultry industry. A large variety of branded feed supplement premix with different type of antibiotics is easily available online and at retail outlets selling veterinary medicines. These are bought and mixed at farms as desired. Ready-to-use pre-mixed feed is also available which is manufactured and sold by feed mills.

The 2007 poultry feed standards of Bureau of Indian Standards (BIS) recommend not using those antibiotics which have systemic action as growth promoters in feed.[5] Doxycycline and tetracycline have systemic action i.e. they target more than one site and do not act locally. However, the standards are voluntary and non binding. Further, the standards mention phasing out gut-acting antibiotics, which primarily target the gut, in five years. However, as per the response from BIS, no further action has happenned in this regard till date.

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Recently, in June 2014, the Ministry of Agriculture issued a circular requesting states to advice veterinarians on judicious use of antibiotics.[6] It also mentioned that use of antibiotics in feed is to be stopped. However, there are no specifics around how it would be implemented and monitored. It only talks about conducting awareness programmes if required. There is no mention of the alternatives and timelines.

**Routine use of antibiotics for disease prevention; no mandatory provisions for farm hygiene and sanitation**

Antibiotics used in humans are also used in animals. Broiler farms administer routine preventive doses of antibiotics to prevent infections. Antibiotics such as ciprofloxacin are easily available without any prescription and labels in markets of Delhi. These are unlicensed and are either imported from China, or sold to bulk-drug markets by pharmaceutical manufacturers in India. These could be expired.

There are no mandatory provisions covering farm sanitation and hygiene. The biosecurity guidelines meant for Central Poultry Development Organisations (CPDOs) are not applicable to other poultry farms.[7]

### General Guidelines for Biosecurity at CPDOs

Biosecurity is an integrated approach to analyze and manage risks in the areas of animal health and food safety, including associated environmental risks. Department of Animal Husbandry and Dairying (DADF) came up with a set of general guidelines for biosecurity after the avian influenza outbreak at few Central Poultry Development Organizations in the country. The basic tenets of these guidelines can be applied to State poultry farms also. These include isolation, traffic control and sanitation. An integrated biosecurity programme aims to contain the diseases at a bare minimum level by applying principles specific to enterprise, monitoring of disease status and evaluation of poultry farm operations on a continuous basis. The proposed standard operating procedures to maintain biosecurity include those around farm location and design, restricted access to birds, isolation and quarantine of new birds, cleaning and sanitation, personnel hygiene, hygienic disposal of poultry manure, disposal of dead birds, feed safety, period of rest or rearing of single age group, medication/vaccination of birds, flock profiling, documentation and record keeping.

**No effective framework to reduce the use of antibiotics, neither targeted at farmer and nor at the veterinarians**

There is no provision to monitor the type and quantum of antibiotics prescribed by veterinarians. Neither there is a mechanism for mandatory veterinary supervision of the farms. The National Livestock Policy, 2013 barely mentions about antibiotic resistance. It only maintains that states would be encouraged to promote judicious use of antibiotics.[8] There is no monitoring mechanism that ensures that veterinary prescriptions are in line with judicious use of antibiotics and are updated based on latest trends in resistance in antibiotics.

As per a 2013 circular by Drug Controller General of India, it is mandatory to mention withdrawal periods on the labels of antibiotics meant for animal use.[9] In case it is not labelled, it is set for 28 days for chickens, which is not followed. Provision for monitoring antibiotic residues are only available for exports under the Residual Monitoring Plan of the Export Inspection Council.[10] There are no Maximum Residue Limits (MRLs) set for chickens for domestic consumption.

### Standards based on antibiotic residues do not address ABR in totality; resistant bacteria should be considered as an adulterant

Standards for maximum residues of antibiotics partly address the cause of ABR. They focus on one part of the problem that is Maximum Residual Levels (MRLs) of an antibiotic allowed in a particular food commodity or a tissue, say muscle and liver of chicken. They are based on toxicity of antibiotics and are set to prevent against it.[11] However, the presence of resistant bacteria and genetic material in food, a leading cause of spread of ABR goes unchecked. It should be considered as an adulterant, a demand which is gaining ground in the US, wherein a non-profit in the US, Centre for Science in the Public Interest wants the US Dept. of Agriculture (USDA) to declare certain strains of antibiotic resistant *Salmonella* in ground meat and poultry as adulterants.[12]

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**TABLE 1: Details on regulatory initiatives and shortcomings to address antibiotic resistance**

| Initiative | Details | Shortcomings/Gaps |
|---|---|---|
| Bureau of Indian Standards – Poultry Feed-Specification – fifth revision 1374:2007 | Recommends not using antibiotics with systemic action as AGPs in feed. These include chloramphenicol, doxycycline, tetracycline, nitrofuran, furazolidone. Also mentions phasing-out of gut acting antibiotics in five years. | These standards are not mandatory. No revised standard on gut acting antibiotics. It has been seven years already. |
| Food Safety and Standards (contaminants, toxins, and residues) Regulations, 2011 | Maximum residue limits (MRLs) of select four antibiotics is set for sea foods including shrimps, prawns. Antibiotics are tetracycline, oxytetracycline, trimethoprim and oxolinic acid. Also, use of certain antibiotics in seafood processing units is prohibited. Prohibited antibiotics include nitrofurans, glycopeptides, chloramphenicol, neomycin, fluoroquinolones and select sulfonamide drugs. | The regulation is not applicable to poultry industry. They only cater to the antibiotics used in aquaculture. Besides, MRLs are set for only select antibiotics. There is a need to include more antibiotics. However, residues of certain antibiotics are stated to be monitored in poultry only in case of exports under the residue monitoring plan for fresh poultry meat and poultry meat products 2011-2012 of the Export Inspection Council. |
| National Policy on containment of antimicrobial resistance, 2011 | Policy mentions about the need for developing regulations on usage of antimicrobials in poultry as well as the requisite labelling requirements in food. It also talks about surveillance of resistance, promoting rational antibiotic use through education, monitoring, and supervision and researching new drugs. | While there is limited progress on several aspects since 2011, the policy does not consider the need for monitoring resistance in animals and related products in food chain. Such integrated surveillance is a part of programmes of several EU member countries and is considered essential. Also, there is limited information in the public domain about the actions planned and initiated for use of stakeholders. |
| National program on containment of antimicrobial resistance, 2012-17 | Aims to establish a laboratory-based surveillance system in the country, generate awareness on rationale use of antibiotics and strengthen hospital infection control guidelines. | Agreements with only 10 laboratories in eight cities has been signed so far. Data collection has not yet started. About 30 labs are planned to be associated, however there are no concrete timelines. |
| Drugs and Cosmetics (Fourth Amendment) Rules, 2013 | A new schedule H1 for antibiotics along with certain other drugs is introduced. It is to monitor and regulate the human overuse of antibiotics. It requires pharmacists to maintain drug name, prescriber's name and address; patient's name and quantity supplied should be maintained for three years and be open for inspection. Also the drug formulation will have to be labelled with 'Rx' accompanied with a warning on the box. It is not to be sold without the prescription of a Registered Medical Practitioner. | There is no such provision for veterinary drugs to monitor and regulate the overuse of antibiotics. |
| Circular regarding sub rule 3A of rule 97, Drugs and Cosmetics Rules, 1945, 2013 | The container of the medicine for treatment of food-producing animals shall be labelled with the withdrawal period of the drug for the species on which it is intended to be used. If the specific withdrawal period is not mentioned, it should not be less than 28 days for meat from poultry. | In practice, withdrawal periods are not followed implying that the monitoring of antibiotic residues is ineffective. Also, the provision does not take care of non-therapeutic administration of the antibiotics. |
| Circular to state animal husbandry commissioners by Department of Animal Husbandry and Dairying, June, 2014 | The Ministry of Agriculture issued circular requesting states to advice veterinarians on judicious use of antibiotics. It also mentioned that use of antibiotics in feed is to be stopped. | There are no specifics around how it would be implemented and monitored. It only talks about conducting awareness programmes if required. Neither there is any mention of the alternatives nor of timelines. |

***Source:*** *Bureau of Indian Standards; Food Safety and Standards Authority of India; Directorate General of Health Sciences; National Centre for Disease Control: Central Drugs Standard Control Organisation*

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