Cornell Sathguru Foundation for Development

1st One Health India Summit
Position Paper

Acknowledging Challenges and Paving the Way Forward

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Contributors

Pushpa Vijayaraghavan, Director and Practice Lead - Healthcare
Aparna Balasubramanian, Senior Consultant
Shree Divyya, Senior Consultant
Ayush Naulakha, Associate Consultant

Sathguru has wealth of experience and knowledge in strategy, investment banking, innovation access and advancement and across the continuum of agribusiness, food, animal health and human health. For any comments or discussions, please reach out to the authors at pushpa@sathguru.com or lifesciences@sathguru.com

Supporting Partners and Contributors

Dr Prejit Nambiar, Assistant Professor and Officer-In-Charge, COHEART, Kerala Veterinary and Animal Sciences University (KVASU)
Dr. Subeer Majumdar, Director, National Institute of Animal Biotechnology (NIAB)
Dr. Nagendra R. Hegde, Scientist, NIAB
Dr. D.K.Dey, CEO, Globion India Pvt. Ltd
Dr. Niraj Warke, Vice President -Regulatory & QA, Globion India Pvt. Ltd
Prof. P. Reddanna, University of Hyderabad

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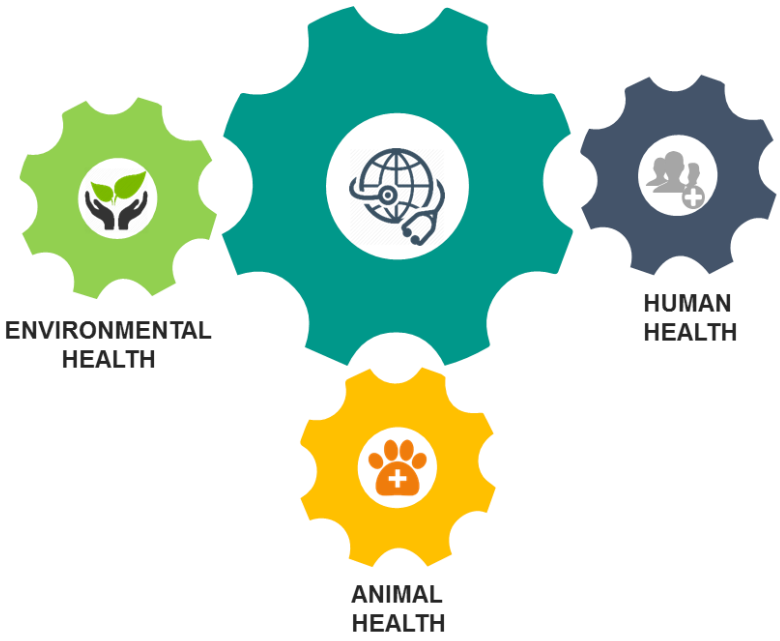
I. The Concept of One Health

We live in an era where the interconnectedness of human health, animal health, and environment can no longer be ignored. The idea of the "One Health Concept" is, in essence, to appreciate the wealth of opportunity that lies in the interface area of this triad, which could be capitalized on, to protect the health of our planet as a whole. This One Health Concept is critical to attaining the vision of FAO, OIE and WHO of 'a world capable of, detecting, responding to, containing, eliminating, and preventing animal and public health risks attributable to zoonoses and animal diseases with an impact on food security through multi-sectoral cooperation and strong partnerships'.

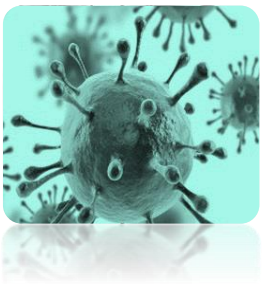


The need for robust inter-sectoral governance mechanisms to prevent and prepare for public health risks of animal origin has long been identified as priority by international organizations ever since the first Veterinary Public Health international programs were established at WHO and PAHO in the 1950s (WHO, 1970). It is especially critical to be implemented in the context of developing countries such as India where several looming health issues call for an integrated approach with cross-stakeholder engagement.

Key Themes defining One Health in the Indian Context

The main themes that characterize the concept of One Health in the Indian context, which are also the top issues that call attention for a unified One Health approach towards solutions are identified below:

Anti-Microbial Resistance (AMR)



Negating the impact of great strides made in anti-infective therapies and vaccines, the excessive use of antibiotics in humans have already created super-bugs that resist treatment, baffling healthcare practitioners and scientists. Lack of prescription control and continued use of avoidable antibiotics has created significant problem of resistance. There are also repercussions from the food value chain. Use of therapeutic antibiotics is common and advocated in animal health. However, in the absence of Maximum Residue Levels (MRLs) in India for milk, meat and several categories of animal derived food products, the threat of a trickle-down effect of such therapeutic use continues.

Zoonosis

Zoonosis refer to inter-species transmission of infectious diseases. Animal to human transmission is a bigger threat today, with several diseases such as rabies, brucellosis and avian influenza taking center stage. On the other hand, reverse zoonosis is another growing concern with growing disease transmission from humans to animals, with bovine Tuberculosis being recognized as the largest threat today, besides a few other diseases in companion animals. Wild zoonosis also becomes an integral aspect while viewing through the One Health lens, as most of the emerging zoonotic diseases are originating from wild animals, which are almost out of reach for implementing any countermeasures.

Food Safety

With burgeoning incidences of food-borne illnesses, there is growing public awareness of food safety, food security and sustainability in food production practices. Residues of pesticides from foods of plant-origin and residues of antibiotics, toxins and hormones from animal-sourced foods are some of the unaddressed issues that question the very foundation of our farming practices today. On the other end, non-communicable pathogens also find their way to affect human health through the food chain.

Vast expanse of issues surrounding One Health in the Indian context calls for urgent attention to convergent solutions. It is critical that we engage a multi-stakeholder approach to conceptualizing an actionable roadmap in the national context. While embarking on a One Health initiative, we must take cognizance of industry structure and commercial implications and make rapid strides towards adopting required research priorities, policy frameworks and practices.

Overview of Indian Industries that are enfolded in the One Health Approach

II. Indian landscape in Industries that are enfolded in the One Health Approach

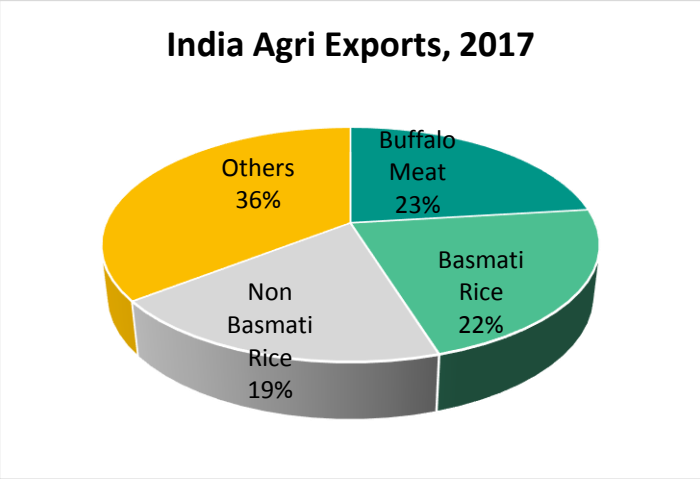
The concept of One Health is multi-disciplinary in nature, pervading multiple industry sectors such as Agriculture and Animal Husbandry at the end-user level and human health, animal health and agriculture inputs at the business side. Thus, the implementation of One Health approach needs an integrated, collaborative co-operation between all these industries. Below is an overview of these inter-connected industries and relative ease of any One Health agnostic change implementation in these sectors. Several factors determine the ease of change implementation for an industry sector, such as:

- Stringency of Regulatory Framework
- Level of Market Concentration - Higher the market concentration, easier is change implementation, considering lower number of entities for enforcement
- Level of end user education and dependence on government extension work/delivery
- Level of industry sensitization to One Health-related issues
- Identification of research priorities
- Openness and willingness for co-operation across sectors

Agriculture Sector

Although India is quickly transitioning from being an agrarian economy to an industrial and service-driven one, the importance of agriculture in the country cannot be undermined. The agricultural sector (including agriculture proper, Livestock, Forestry & Logging, Fishing and related activities) still employs 47% of the country's workforce and contributes to 16.8% of the national GDP[1].

According to APEDA statistics, India recorded USD 17 billion worth of agricultural exports in 2017. Buffalo meat and Rice are the key export commodities of national importance, accounting for 64% of exports by value. However, the export market has been declining over the past 5 year period, mainly due to declining international prices.

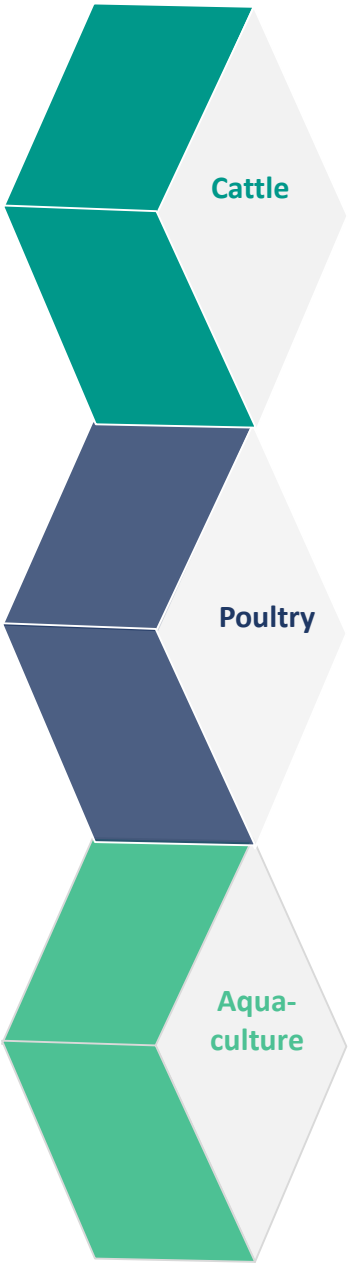


Ease of Change Implementation

[1] Source: CIA Factbook

Animal Health Sector

The Indian animal health industry includes distinct sub-segments with significant differences in level of consolidation and corporatization, adoption of best practices and vaccination in farming, and adoption of contemporary inputs motivated by economic impact and trade implications (especially for exports):

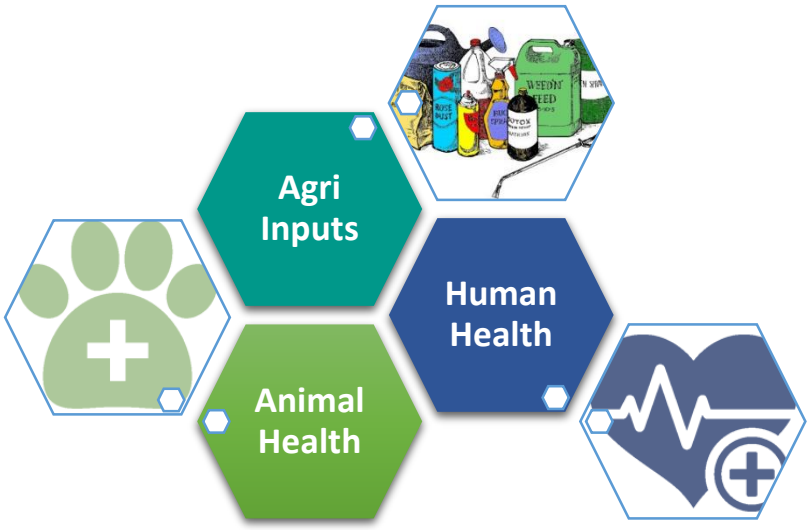


- Highly fragmented market - Segment dominated by small farmers; Average farm size in India is 2 animals
- Market channel demarcated into farmers attached with dairy co-operatives/ private aggregators and private farmers
- Low awareness among consumers about diseases, their impact and economic benefit of preventive approaches
- Low affordability and heavy dependence on government extension programs for vaccination and healthcare

- Consolidated segment with a high level of organized and integrated farming
- High awareness of communicable diseases with potential to wipe out large farms and thus, high focus on vaccination and preventive healthcare
- High level of backward integration in the oligopolistic segment with leading companies engaged across the continuum of feed and other inputs, contract farming and value addition

- High consolidation and organized commercial farming in export-driven shrimp market, while fish culture remains fragmented
- Unlike shrimp farms that enjoy better export price realization, fish farms are more cost sensitive and have low level of adoption of commercial products
- Highly consolidated landscape of input companies, especially for shrimp culture who exert high influence on farming practices

Healthcare and Agriculture- Inputs Industries



Agricultural Inputs

- Fragmented industry, with greater MNC dominance in high technology inputs involving newer generation molecules
- While there is initial thrust from industry to move to more sustainable measures, traditional industry structure and farm practices deter faster market adoption
- Biologic crop protection gaining popularity but still small part of overall inputs used – food security concerns, price sensitivity and small farmer holdings with low willingness to pay impede faster adoption

Human Health

- Highly fragmented industry in the domestic landscape, with relatively more consolidation in regulated market participation
- Anti-infectives including antibiotics is one of the largest pharma markets in India accounting for a dominant share of 29% of total market (Source: AIOCD data, 2015)
- Very low level of end-user awareness on antibiotic resistance
- Continuing industry thrust on vaccines and therapeutics

Animal Health

- Moderate and varying level of cognizance about antibiotic residues in food (low in cattle and dairy, higher in shrimp etc.)
- Moderate level of engagement in developing alternate products for disease control
- Probiotics gaining popularity across some segments such as aquaculture, companion animals and poultry, immunostimulants in aquaculture
- Continued focus on prophylaxis of infectious diseases and thrust on vaccine usage

HIGH | LOW | MEDIUM

Ease of Change Implementation

Overview of Convergent Policy Frameworks Underpinning the One Health Concept

III. Overview - Convergent Policy Frameworks Underpinning the One Health Concept

Although appreciation and implementation of the One Health Concept is still nascent in India, the challenges and issues underpinning it have individually created sufficient impact to have triggered several policy and regulatory measures. Some of the cross-cutting policies and regulations that operate in the convergent realm of human, animal and environmental health are outlined below.

1. Food Safety and Standards Act, India

The Food Safety and Standards Authority of India (FSSAI) under the Ministry of Health and Family Welfare is the main authority for:

- laying down science-based standards for articles of food,
- to regulate their manufacture, storage, distribution, sale and import,
- to ensure availability of safe and wholesome food for human consumption and

for matters connected therewith as per the rules specified by Food Safety and Standard Act, 2006 (FSSA, 2006).

Section 20 and 21 of FSSA, 2006 stipulate the limits for contaminants, naturally occurring toxic substances, heavy metals, pesticides, veterinary drugs residues, antibiotic residues and microbiological counts in food.

Section	Provisions
2.1	Limits for metal contaminants like Lead, Arsenic, Cadmium etc.
2.2	Limits for crop contaminants and naturally occurring toxic substances
2.2.1	i. Crop contaminants (like Aflatoxin, Ochratoxin, Pataulin)
	ii. Naturally occurring toxic substances (like HCN, Saffrole)
	iii. PCBs and PAH compounds in Fish & Fishery Products
2.3	Residues
2.3.1	Restriction on the use of insecticides directly on food & tolerance limits in foods
2.3.2	Antibiotic and other pharmacologically active substances i. Tolerance limits prescribed for antibiotics in seafoods, fish & fishery products; ii. Prohibits use of listed antibiotics in seafoods, fish & fishery products iii. Limits of antibiotics in Honey
2.4	Limits of biotoxins in fish and fishery products
2.5	Other Contaminants
2.5.1	Melamine - Maximum Level prescribed in foods
2.5.2	Limits of Histamine in Fish and Fishery Products

Ambiguity in Regulation for use of antibiotics in livestock: The FSS (Contaminants, Toxins and Residues) Regulations, 2011 only has standards for antibiotics in fisheries & honey under the regulation and currently there is no regulation for use of antibiotics in livestock, or poultry. In November 2017, FSSAI has notified draft of the FSS (Contaminants, Toxins and Residues) Amendment Regulations, 2017 specifying the tolerance limit for Antibiotics used in human beings and animals,

Antibiotics for exclusive use in animals and Other Veterinary Drugs. FSSAI had invited comments from stakeholders on the amendment regulations and the final notification of this amendment is pending. For a long term resolution, it is ideal that a multi-stakeholder approach is adopted for finalizing this critical policy framework with active engagement of the animal health and food industry to evolve MRLs most suitable in the Indian context.

Withdrawal Period for Veterinary Drugs: Stipulation of withdrawal period of the Veterinary drugs used for treatment of food producing animals is required by law. An insertion to Rule 97 of the Drug and Cosmetics Rules, 1945 which came in to force in 17.01.2012 specifies that the container of a medicine for treatment for food producing animals shall be labeled with the withdrawal period of the drug for the species on which it is intended to be used. The withdrawal periods refer to interval between last administration of the drug to animals and production of food stuffs from such animals, so as to reduce the residues of the drug below MRL.

MRLs for Veterinary Drugs: The Codex Alimentarius recommendations are designed to assist countries as they consider adopting national MRLs. The "Maximum Residue Limits (MRLs) for Veterinary Drugs in Foods", updated in July 2015, recommends MRLs for commonly used veterinary drugs, including antibiotics in specific types of animal tissue.

2. Control Programs for Zoonotic and Highly Communicable Diseases

1. **Animal Birth Control- Anti-Rabies Programme (ABC-AR):**

- Rabies - one of the most recognized and popular zoonotic diseases that has garnered significant awareness.
- While until 1998, catch-and-kill was the method adopted for over 100 years to control stray dog population, the Blue Cross of India studied the situation and intervened in 1964, proposing a more humane, sustainable and sensible alternative program of catch-and-neuter plus rabies vaccination, thus giving birth to the ABC-ARV (Animal Birth Control- Anti-Rabies Vaccination) program, developed by WHO as the only practical solution to control the street dog population and eradicate rabies.
- The ABC Rules, 2001 have been issued by the Animal Welfare Board of India (AWBI) and the program is implemented by respective State Governments directing municipalities to work with animal welfare organizations to implement the ABC program with specific sterilization laws. AWBI has submitted a revised ABC module to the Supreme Court pursuant to 2016 Supreme Court orders, but it is still under consideration by the Supreme Court and is not applicable as on date.
- Although there is national wide adoption of the program today and some cities boast of successful implementation (such as South Mumbai with sterilization rate of 73% per the 2014 BMC Survey), there is significant need to further enhance the efficacy of the program in several geographic pockets.

2. **Foot and Mouth Disease Control Program (FMD-CP)**:

FY 2016-2017 - INR 168 Crores released;
172 million Vaccinations done

- Although FMD is not a zoonotic disease, the disease affects all cloven-footed animals (cattle, goat, sheep, and pigs) with high cross-species transmission potential, thus impacting food production.
- Thus, in a country like India with such a sizeable livestock industry, an outbreak of FMD weighs very heavily on economic repercussions (Rs.20,000 Crores annually, according to FAO), thus calling for structured control measures.
- The national FMD Control Programme (FMD CP) was implemented in 2004, in 54 districts, targeting 30 million cattle as well as all pigs in those districts. The Programme has since been extended to 351 districts today, targeting about 197 million animals including cattle and pigs.
- The program has 100% central government funding for administering 2 dose schedule of FMD vaccine, covering vaccine, cold chain and other administrative expenses. It is one of the largest veterinary initiatives and vaccination implementation success in animal health in India.
- However, today it only covers cattle, buffaloes and pigs and does not cover other small ruminants such as goats and sheep which are also susceptible to FMD and could be carriers.

3. **Brucellosis Control Program (Brucellosis-CP):**

FY 2016-2017 INR 2.11 Crores released;
0.7 Lakh Vaccinations done

- Brucellosis is an endemic and deadly zoonotic disease in India, which affects the reproductive health of animals, causing abortions, retained placenta and infertility, thereby proving detrimental to the dairy industry, which depends on year-round calving of milch animals. India being the largest milk producer in the world, the dairy industry is at the heart of the Indian livestock sector.
- Overall prevalence of bovine brucellosis in the country was found to be 2.3% and Nagaland, Punjab, Rajasthan and Telangana were identified as hotspots in the country with Nagaland recording highest prevalence of 25%[2].
- Considering the importance of this incapacitating disease, the government started the Brucellosis-CP in the year 2010, enabling mass vaccination of all female calves of age between 6-8 months in areas of high incidence. The program also supports periodical surveillance through biannual village level screening of pooled milk samples.

[2]NIVEDI Annual Report 2015-2016

- The Department of Biotechnology, Ministry of Science and Technology, Government of India has also initiated a Network Project on Brucellosis to study the epidemiological status of Brucella infections in India and to develop novel diagnostics and vaccines.
- However the vaccination program today does not cover small ruminants and the coverage for routine vaccination of large ruminants is also found to be sub-optimal.

Brucellosis is also a debilitating disease of humans, especially those that handle animals and meat. Unfortunately, recognition of human brucellosis among medical fraternity is poor, leading to misdiagnosis. In addition, treatment is prolonged, and with side-effects.

4. Peste de Petits Ruminants Control Program (PPR-CP):

FY 2016-2017 INR 4.7 Crores released;
15.34 million Vaccinations done

- Predominantly found in small ruminants such as sheep and goats, PPR is a viral communicable disease that causes gastro-enteritis, oculo-nasal discharge and sometimes, pneumonia.
- The disease is characterized by up to 100% morbidity and 90% mortality, thus calling for concerted prophylactic measures.
- The PPR-CP was started in 2010 for intensive vaccination of susceptible animals, with 100% funding assistance from central government. Initially introduced in 6 high-incidence states and 5 union territories, the program was later extended to all states under the 12th 5-year plan (2012-2017).

5. Classical Swine Fever Control Program (CSF-CP):

FY 2016-2017 INR 0.57 Crores released;
66.7 thousand Vaccinations

- Swine fever is endemic to most pig producing parts of the country and is also a zoonotic disease with widespread human outbreaks in the country.
- A relatively newer program, the CSF-CP was added to the Livestock Health and Disease Control (LH&DC) Schemes in 2015, supported by 90% central funding.
- The program has been started in a phased manner, beginning in the north eastern states with 100% funding for the CSF vaccines, where disease prevalence is highest, and planned for gradual expansion nationally based on vaccine availability and supply security with central and state funding.

6. **Assistance to States for Control of Animal Diseases (ASCAD) Programme:**
    - Apart from the above central level programs providing support for control of individual diseases, the ASCAD program provides support to governments of states and union territories for specific control of zoonotic diseases, which are not covered under the central programs.

FY 2016-2017 INR 30.35 Crores released;
165 million Vaccinations done

    - This is a more flexible component that could be directed towards better vaccine coverage or towards ramping up support capabilities. For example, in Haryana and UP, ASCAD provides FMD vaccination in districts not covered by FMD-CP, while Maharashtra has utilized ASCAD funding for modernization of diagnostic facilities.
    - The program is implemented in a 75:25 shared funding between central and state government, except in north eastern states where the fund ratio is 90:10.

3. Trade Policies Affecting Indian Agricultural Practices

India's export of fresh and processed food products (including agriculture and allied products, marine products and plantation products) was USD 0.40 billion in 2016-17

While exporting, India has to follow the standards and requirements laid down by all its importing countries. According to the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), every country has the right to set and implement food safety and health standards provided they are based on scientific justification and are implemented to protect human, animal or plant life. SPS agreements require National Standards to Harmonize with International standards.

Many developed countries impose more stringent standards than globally acceptable standards such as the Codex Alimentarius standards, which can act as non-tariff barriers to exports from developing countries. Pesticide MRLs are primarily trading standards and not safety levels as they are usually set much lower than the levels that would pose a risk to consumers, generally 100 times below the no observable effect level. MRLs for the same pesticide-commodity combinations are sometimes different in different countries, creating barriers to trade.

National Residue Control Plan (NRCP) is a statutory requirement for exporting to EU countries. EU food safety policy as 178/2002/EC for food and feed with integrated "farm to fork" approach, aims to harmonize existing national requirements in order to ensure the free movement of food and feed in the EU. For import from non-EU countries, European Commission (EC) seeks guarantees equivalent to EC requirements on residues of veterinary drugs, pesticides and contaminants. The Export Inspection Council (EIC) of India is implementing NRCP through MPEDA in aquaculture products. EIC also implements Annual Residue Monitoring Plans (RMP) for export of Egg Products, Milk Products, fresh poultry meat & poultry meat products and honey to EU.

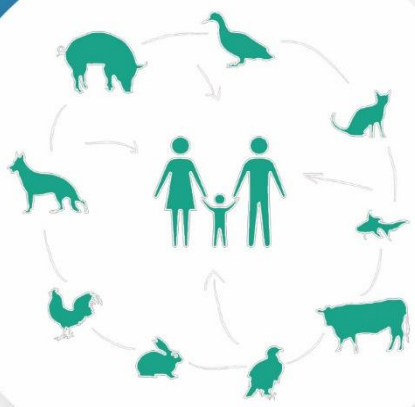
A number of Indian consignments to US and the EU have faced notifications, rejections and alerts due to the presence of higher than approved levels of pesticide residue.

Impact of SPS and Technical Barriers to Trade measures on Indian food exporters:

i. In the short run, export rejections and product bans result in financial losses for exporters and farmers.
ii. In the long run, the product bans can also result in India losing markets to suppliers from other countries having better safety and quality systems.
iii. Increased costs of production due to compliance with product standards, sometimes different compliance requirements in different countries.
iv. Delays at the import stage due to inspection and testing processes, critical for perishables/ products with shorter shelf life.

With growing importance of export markets, exporters and Indian farmers have started implementing measures to meet the International standards, some of which are described below:

i. Good agricultural practices (GAP) are being advocated at the farm level for products meant for export. Exporters and farmers in India have started practicing judicious usage of agrochemicals, usage of biofertilizers and safer pesticides etc. for catering to export markets.
ii. Exporters are working on improving the produce traceability. Establishment of product traceability (use of TraceNet) in products such as grapes for key export markets like EU has helped in resolving SPS issues.
iii. Exporters are upgrading their safety and quality systems, SOPs etc. to meet the pre-compliance requirements for certain geographies; for instance required certifications from EIC for accessing EU markets.
iv. Exporters are also adopting multiple voluntary standards to instill confidence in their customers in different geographies, about their manufacturing / production practices.
v. Increased customer audits in the industry is also helping the exporters in continuous improvement of their safe manufacturing practices and meeting the regulatory/ compliance requirements of various countries.



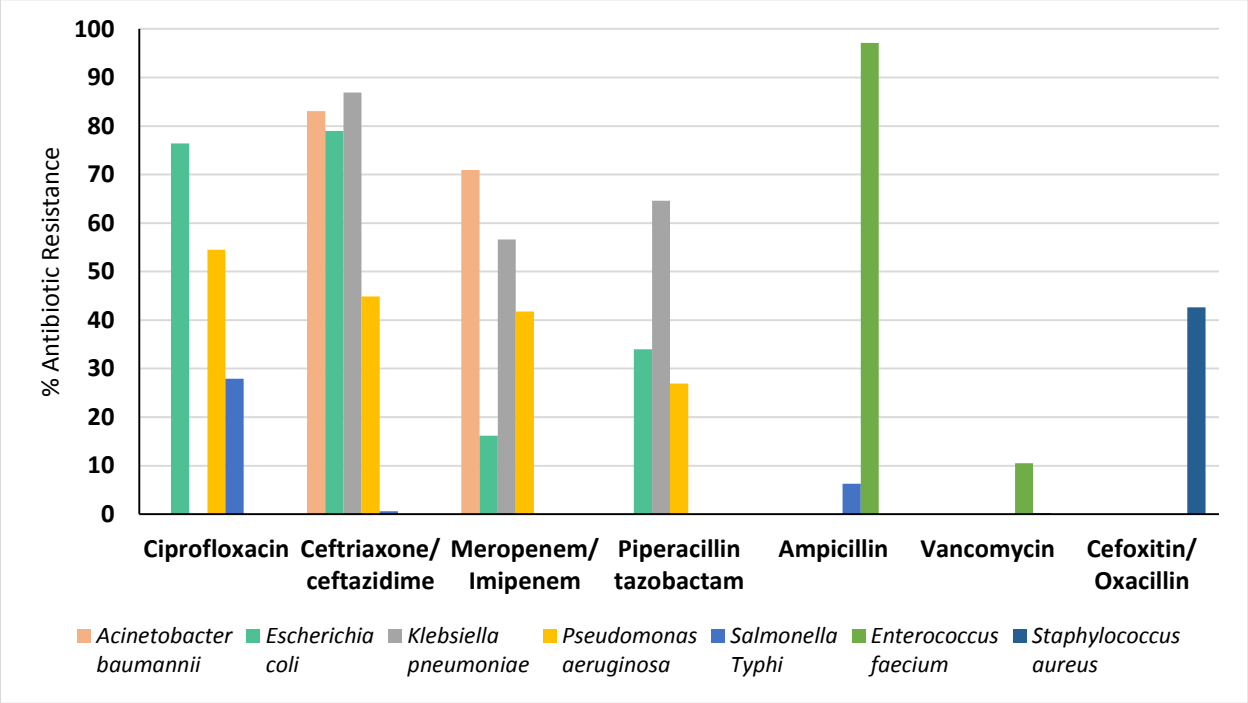
Challenges/ Themes calling for One Health Attention

IV. Challenges/ Themes calling for One Health Attention

Several looming global health issues, as described below, are anchored at the interface area of human and animal health, calling for urgent attention to the concept of One Health. While none of the below discussed issues are alarmingly new at the individual level, greater attention to integrative solutions with a multi-stakeholder approach is needed to implement effective solutions. It is imperative to gain a deep-rooted understanding of these critical issues in order to implement the One Health Approach in the Indian context.

Anti-Microbial Resistance (AMR)

Antibiotics remain the cornerstone of treating infectious diseases of bacterial origin, and yet, today it is increasingly proving to be a bane than the boon that it was. With abusive use of antibiotics at multiple levels of the food chain as well as in human medicine, and the potential release of compounds through industrial effluents, AMR is looming as one of the cross-cutting challenges across the human and animal health continuum today. Data from Indian Council of Medical Research (ICMR) suggests that more than 70% *Enterobacteriaceae*, including *Salmonella, E. coli, Yersinia pestis, Klebsiella, and Shigella* are resistant to third-generation cephalosporins. Some of the top disease causing bacteria and their level of antibiotic resistance as studied by ICMR is depicted below.



Even deadly infectious diseases such as tuberculosis are increasingly being susceptible to AMR.

According to WHO, Extensively drug-resistant tuberculosis (XDR-TB), is resistant to at least 4 of the core Anti-TB drugs and 6.2% of people with Multi drug-resistant (MDR)-TB have XDR-TB

The problem of AMR stems from 2 main issues.

- **Overuse of Anti-microbials in Humans:** Pervasive use of anti-microbials in humans for even minor illnesses has rendered several strains of bacteria to develop resistance to anti-microbial therapies (antibiotics). Over prescription of Fixed Dose Combinations (FDCs) even in cases with uncertain benefits over single compound antibiotics played a major role in the evolution of this problem in India. Compounding these are frequent discontinuation of recommended schedule, over the counter usage, off-label use, and use of expired drugs. Thus, the diseases caused by resistant strains evade treatment, thereby posing a looming healthcare burden.

Use of Antibiotics in India has gone up from 3.2 billion defined daily doses (DDD) in 2000 to 6.5 billion in 2015 making E.coli, Pneumonia and Tuberculosis causing agents to become resistant to anti-microbial treatment[3]

- **Antibiotic Use in Food Animals with no implemented MRL:** In the absence of mandated levels for maximum antibiotic residue, use of therapeutic antibiotics in farm animals such as fishes, poultry, cattle etc., also results in a trickledown effect on the food chain with traces in processed animal food products such as dairy. When meat and other derived food from animals infected with resistant strains, are ingested by humans, it directly results in ingesting the resistant strain which had evaded treatment. It is important to create definitive policy framework and ensure implementation thereof to deter any practices of antibiotic abuse. Policy gaps need to be bridged and a multi-stakeholder consultation approach should be adopted to finalize and roll out the currently draft FSS (Contaminants, Toxins and Residues) Amendment Regulations, 2017 in a manner that is appropriate for the Indian landscape. Further, change in farm practices and compliance should be encouraged through consumer education on the demand side and improved farm practices should be fostered through an appropriate commercial reward ecosystem.

Challenges Compounding the AMR problem

- **Inadequate Surveillance and Regulatory Monitoring of antibiotic usage:** The regulatory landscape surrounding AMR is still evolving in the country and there is need to enhance implementation of existing regulations as well. For instance, FSSAI stipulates a ban on use of several antibiotics as part of standards set in 2011 in any unit processing sea foods such as shrimp, prawns and any kinds of fishes. The banned antibiotics include all nitroflurantoins, sulfonamides, fluroquinolones among others. While the shrimp farming sector is highly compliant today to the use of antibiotics, the situation in fish farming is nowhere near that. This disparity mainly stems from the difference in value realization and target markets for the two sectors. Shrimp farming in India is a heavily export-driven market, and there is very high scrutiny around antibiotic residues implemented by the countries targeted for export, in turn driving consciousness in the use of antibiotics. Fish farming on the other hand, is a largely domestic sector with low level of exports. Thus, rampant use of antibiotics in fish farms reflects poor domestic enforcement of the regulation in the country. It is possible that resistant bacteria arising from use of antibiotics in fishes may contaminate water bodies, leading to rapid movement of such bacteria across terrains and landscapes.

- **Lack of prescription regulation of human antibiotics:** Despite being Schedule H drugs, most antibiotics can be accessed without prescriptions in India, rendering their access fairly open to all. This has resulted in excessive use of antibiotics in human health as well as animal farmers easily accessing large volumes of the drugs from human pharmacies for use on animals. A study published in 2013[3] assessed the over the counter sale of antimicrobials in pharmacy outlets in Pune, India using simulated client methodology and reported the following.

  - **92% and 96% of the pharmacies dispensed antibiotics for sore throat and acute diarrhea without a prescription**
  - **Only 64% and 10% of the pharmacies dispensed correct doses and durations for sore throat and acute diarrhea respectively**
  - **Only 2% enquired about prior allergies**

  Thus, there is high level of awareness that needs to be built among Indian pharmacists about issues surrounding AMR and regulations surrounding OTC medications and implementation of prescription control need to be strengthened in order to address the problem of AMR at its core.

The Way Forward

- **National Action Plan (NAP) on AMR – marks a Significant Beginning:** In response to WHO's Global AMR Action Plan, the Indian Government has put forward the National Action Plan on Antimicrobial Resistance (NAP-AMR) in April 2017, which prioritizes six areas for strategic implementation
  - Awareness through communication
  - Education & Training
  - Strengthening surveillance
  - Promote investments in AMR initiatives
  - Strengthening India's leadership on AMR
  - Reducing the incidence of infection through effective infection prevention and control

  Dedicated collaborative centers are planned to be assigned in the areas of stewardship, surveillance and awareness and ICMR plans to initiate the program in phased manner across smaller in-patient centers. As the first step, ICMR has set up a joint initiative with Pfizer in Delhi, which will implement a series of interventions, ranging from AMR stewardship programs for nursing homes to scaling up of the ongoing AMR surveillance network and creating awareness around responsible use of antibiotics. An awareness and advocacy programme is also to be organized to share information on antibiotic resistance, promote rational use of antibiotics, encourage infection-control techniques, and organize conferences and awards to recognize best practices. The NAP marks a significant first step in terms of government communication on the topic of AMR is a platform that calls for convergent efforts from all relevant ministries and departments to take a One Health Approach to handle the problem.

[3]Salunkhe, S.D. & Pandit, V.A. & Dawane, Jayshree & Sarda, K.D. & More, C.S.. (2013). Study of over the counter sale of antimicrobials in pharmacy outlets in Pune, India: A cross sectional study. International Journal of Pharma and Bio Sciences. 4. P616-P622.

- **Continued Industry thrust on alternate therapies and products**: The human as well as animal pharma industry in recent times have risen to the situation, acknowledging gravity of the AMR issue. There is significant thrust on both – promoting responsible use of antibiotics as well as developing novel drug solutions or platforms to address problems associated with AMR. In human health, India today boasts of pioneering startups developing novel antibiotics for resistant infections including Vitas Pharma in Hyderabad and Bugworks Research in Bengaluru. Amongst the larger pharmaceutical companies, Wockhardt boasts of a novel antibiotic program that was granted fast-track designation by the USFDA.

  In the animal health end of the spectrum, industry has been actively pursuing alternatives such as probiotics and plant extracts or phytobiotics for their diverse pharmacological activities, such as antimicrobial, anti-inflammatory, and antioxidative properties. Plant extracts, such as tea tree oil and its active component, terpinen-4-ol, have demonstrated efficacy in bovine mastitis treatment. As an alternative to in-feed antibiotics, the trend of prudent usage of antibiotics, phytobiotics and non-antibiotic growth promoters in animal feed has been growing in recent past. Another example of alternative product category being explored includes immunostimulants used mainly in the aquaculture segment which stimulates the immune system and imparts non-specific disease resistance.

- **Addressing policy and related infrastructure gaps in animal health:** Regulations surrounding antibiotic and other pharmaceutical residues in animal derived foods has so far been lean and ambiguous in the country. Absence of Maximum Residue Levels for most categories of products is a major policy gap that needs to be addressed. While FSSAI's draft notification on the FSS (Contaminants, Toxins and Residues) Amendment Regulations, 2017 specifying the tolerance limit for Antibiotics used in human beings and animals is a very welcome move in this backdrop, intended impact will be elusive until it is steered to effective implementation. Such MRL should be finalized in consultation with all stakeholders and adapted at levels reasonable for India. In addition to MRLs being mandated, testing facilities will need to be created within proximity to farms and an ecosystem of compliance will need to be created. Policy framework needs to be strengthened on the supply as well as demand side and needs to be supported by implementation infrastructure.

- **Triggering Better Control at the Demand Side:** In a developing country such as India, food security often takes precedence over food safety; and farm practices are heavily influenced by end user demand, awareness and potential for commercial reward across the value chain for improvements adopted. Enhanced regulatory framework on labeling provisions can allow farms with better practices and higher quality produce to position their products accordingly and gain commercial reward.

  The shrimp farming sector is a good example of more effective regulation of antibiotic usage. Our primary research indicates that this was accomplished through efforts of Indian Government as well as farm practices influenced by economic impact of potential export rejections of shrimp with antibiotic residues. This illustrates that triggering control of antibiotic use and promoting adoption of alternate products and practices through demand side interventions - regulations, trade policy and consumer education is also essential to tackle AMR across the value chain.

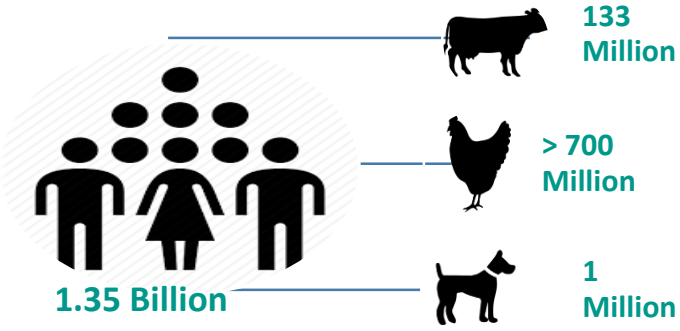
- **Cross-cutting Research:** Another need of the hour is for scientists from across various disciplines such as biology, earth sciences, sociology, economics, health systems, policy & regulations, law etc. to come together in addressing the problem of AMR in an inter-disciplinary, inter-dependent, holistic manner.

Zoonosis, Vaccines & Surveillance

Many zoonotic diseases contribute significantly to global disease burden, including rabies, brucellosis, anthrax and avian influenza to name a few. Diseases caused by helminths, parasites and prions are also emerging zoonotic threats growing increasingly in their significance.

60% of all disease causing pathogens are of animal origin and 75% of emerging infectious diseases are zoonotic in nature[5]

When the high population density of India, large livestock farming community in the country with close proximity due to backyard farming practices and the burgeoning rate of pet adoption are all put together, the propensity of animal-human interactions is far higher in the country than many other countries, making India a global hotspot for zoonoses. According to a study conducted by International Livestock Research Institute (ILRI), India ranks high in zoonotic disease burden along with low income countries such as Ethiopia, Nigeria, and Tanzania. There are many dimensions to zoonosis in the Indian context, as detailed below:



Controlling Zoonosis at the Animal Source: Science has today advanced to a level that prophylactic as well as therapeutic options exist for most of the zoonotic diseases that have evolved, yet, controlling these zoonotic pathogens at its animal source remain a big broken thread in the continuum. Looking at farm animals, there is significant industry thrust today on vaccine prevention of major diseases with propensity to impact farmer business. However, milder zoonotic diseases with lower disease threat to the farm are typically not given importance for preventive measures. There also exists a void in farmer awareness that complicates the issue. While farmers are largely aware of the main zoonotic diseases that can be contracted from their farm animals, there is low attention to paid to the modes of transmission and preventive measures to be taken. There is also a laid-back attitude in proper first aid and disease treatment which inevitably results in rapid dissemination of the disease within the human community. In essence, it is evident that today, the current approach towards zoonosis is such that treatment at the human level is given more importance than prophylaxis at the animal level. Rabies is a classic example, where the post exposure human rabies vaccine market is at least as large, if not larger, than the dog vaccines market, thus exemplifying this approach.

Wild Zoonosis: While the threat of zoonosis is more pronounced in India in the case of farm animals and companion animals, zoonoses with a wildlife source can hardly be ignored today and present a latent less-appreciated disease burden. Ecological changes such as deforestation have not only caused detrimental impact on the environment, but has also triggered wild animals to come into higher contact with domestic animals and humans, opening the channel for transmission of microorganisms between humans, domestic animals and wildlife. Insect vectors also play a crucial role in transmission of wildlife zoonoses. Several deadly zoonotic diseases that are endemic to Asia such as Crimean-Congo hemorrhagic fever (CCHF), and Kyasanur Forest Disease (KFD), have their origin in the wildlife.

CCHF is a viral disease transmitted to humans through ticks and livestock animals, with upto 40% mortality rate during an outbreak. While the disease is asymptomatic in affected animals, it has serious effects on humans, causing multiple organ failure. The latest outbreak in India happened in Ahmedabad in 2011 with a death toll of 3. There are currently no vaccines for CCHF.

KFD on the other hand is a more India-relevant zoonotic disease with an incident rate of 400-500 cases in India every year with seasonal outbreaks in the Western Ghats region. Originated in the Kyasanur Forest in Karnataka, KFD is a tick-borne viral disease that is transmitted to humans from animal reservoirs. Popularly called as monkey fever, the disease causes long bouts of fever accompanied by diarrhea, mental disturbances and vision losses. Originated in the state of Karnataka, the disease has now spread to Kerala, Goa and Maharashtra as well.

Reverse Zoonosis: Finally, the problem of reverse zoonosis - transfer of disease from humans to animals is a significantly growing concern, with Tuberculosis (TB) being a case in point in the Indian context. While Mycobacterium Bovis, a strain originated in cattle constitute a zoonotic threat to humans, Bovine TB caused by Mycobacterium tuberculosis is a severe and less understood reverse zoonotic problem. As such, TB is one of the deadly infectious diseases in India, with an estimated 28 lakh new cases of TB in 2016, with over 4 lakh people succumbing to the disease[4]. The disease is also marred by challenges on the vaccine front as well, with BCG, proven to be inefficacious thereby necessitating better candidates for the future. Thus, bovine TB further exacerbates the problem by creating a transmission loop which makes the disease so much more difficult to eradicate. There is cognizance of this massive problem, with a collaborative project funded by the Bill & Melinda Gates Foundation and the Department of Biotechnology recently being undertaken by Tamil Nadu Veterinary and Animal Sciences University (TANUVAS) to assess the current status of bovine tuberculosis in India.

> M. bovis accounts for 0.5 to 7.2 per cent of human tuberculosis cases in industrialized nations and is estimated to be responsible for 10 to 15 per cent of new cases in the developing world[4]

Other zoonotic diseases that are globally reported to be transmitted from humans to animals include methicillin-resistant *Staphylococcus aureus* (MRSA), influenza A virus, *Cryptosporidium parvum*, and *Ascaris lumbricoides*.

The Way Forward

- **Surveillance and Reporting Outbreaks – a missing link:** In the case of farm animals, surveillance and reporting of disease outbreak is in itself a missing link today, triggered by fear of farmers'

[4] Government Data

business continuity or sometimes even by paperwork related hesitancy of reporting officials. Thus, there is a large looming need today to bridge gaps in surveillance and increase efficacy of systems to ensure that occurrence of known zoonotic diseases are mapped and that emerging zoonotic diseases are identified. This is a fundamental for making informed vaccination policies and enforcing adoption. While there is some level of success today in disease surveillance programs, individually at the human and animal level, such systems fall short in tracking the chain of transmission at the interface of zoonosis. While there has some been government thrust in this direction, even if not specifically for zoonotic diseases, with the National Animal Disease Reporting System (NADRS), a recent Center sponsored scheme for a web-based IT system introduced in 2013, the momentum for implementation needs to be strengthened multifold. Besides addressing surveillance issues in the country for the identified zoonotic diseases, it is crucial to also actively track the status of other globally emerging zoonotic diseases so that outbreaks such as Zika Virus disease are less likely to catch us unprepared.

- **Establish a powerful transboundary network of partner institutions** across India that is involved in education and research related to zoonotic and infectious diseases of humans and animals, a network addressing the growing importance of vector-borne diseases at a time of Global Change, all integrated under the One Health concept, and reflecting the complexity and demands of current high end research. There is a need to create a framework for collaboration to improve surveillance and monitoring of emerging vector borne viral diseases (such as arboviruses) and work towards setting up physical or virtual centers for zoonosis and public health.
- **Building Farmer awareness**: Significant work needs to be done in awareness creation and inculcating a cultural change in the farmer community in order for better reporting of disease outbreaks, which is a crucial step in breaking the zoonosis cycle of disease communication. Strengthening of measures to incentivize farmers for loss incurred due to disease outbreak could go a long way in building farmer trust and security and alleviating threat of business continuity, thereby paving way for culminating spread of zoonotic diseases.
- **Improving Vaccination Coverage for Zoonotic Diseases:** Rabies, and brucellosis are the top zoonotic diseases of high concern in the Indian context, followed by bovine TB.
    - **Rabies**: While the ABC program has made significant strides in stray dog rabies vaccinations, the level of success of the program is highly variable across the country. Statistics on successful implementation (such as sterilization rate and dog to man ratio) should be published at a national level, operational challenges of Animal Welfare Organizations (AWOs) implementing the program need to be addressed and minimum sterilization and vaccination rate of 70% (as recommended by The Global Alliance for Rabies Control and the 2014 FAO report on consultation on dog population management) should be targeted across states to ensure rate of sterilization and vaccination can outpace reproduction.

      According to WHO, 87% of rabies cases in animals appear in dogs, and more than half of the global deaths resulting from rabies occur in India
    - **Brucellosis:** The recently introduced national control program for Brucellosis is a welcome development that depicts government attention to this zoonotic disease. On the diagnostics end,

      Brucellosis causes more than 500 000 human infections per year

[5] Mayada Gwida et al, Croat Med J. 2010 Aug; 51(4): 289–295

adequate facilities are today in place, with TANUVAS launching a highly sensitive and affordable ELISA based Point of Care (POC) diagnostic kit in 2016 which is effective on both human as well as bovine population. However, the effectiveness of the control program has abundant scope of improvement, mainly because of poor vaccination coverage today. Considering female cattle population in the country is about 133 million[6], the Brucellosis program only achieved 0.7 lakh vaccinations in the 2016-17 period, which was directed at female cattle in the 6-8 month age group only in high incidence areas. The vaccination momentum needs to be enhanced multifold to attain a meaningful efficacy for the program.

- **Bovine TB:** This has been one of the long-ignored problems in the country which is not given due importance. There has been a severe dearth of data pertaining to incidence of this reverse zoonotic disease and there has been no vaccination focus thus far. While the world's End TB strategy has a target of the year 2030 for elimination of TB, the Indian government is more ambitious and is aspiring for a TB free India by 2025, as recently announced by the Prime Minister at the Delhi End TB Summit in March 2018. However, the issue of reverse zoonosis could put a damper on this lofty target if the issue is not addressed with a One Health approach. It is imperative to break the loop of zoonotic transmission in order to pave the way for a TB free India.

According to WHO, an estimated 8.8 million cases of human TB results in 1.5 million deaths globally in 2010 and India alone accounted for an estimated one quarter (26 per cent) of all TB cases worldwide.

About 1000 Indians die from TB per day at the rate of one per minute and 95% of new TB cases are seen every year[8]

Food Safety

Food safety is another integral issue that is at the heart of the One Health Concept, as the food chain inevitably interlinks the worlds of humans, animals and environment. Food-borne diseases are a major health burden leading to high morbidity and mortality globally. The most frequent causes of foodborne illness were diarrheal disease agents.

WHO (2015) estimated the global burden of foodborne disease as 33 million Disability Adjusted Life Years (DALYs), with 40% of the foodborne disease burden among children under 5 years of age. Together, the 31 global hazards caused 600 million foodborne illnesses and 420,000

Data for the period 2011-16 from India's Integrated Disease Surveillance Programme (IDSP) shows that food-borne outbreaks together with acute diarrhoeal diseases constitute nearly half of all reported outbreaks under IDSP (CD Alert, March 2017). A review of recorded foodborne disease outbreaks in India from 1980 to 2016 shows *Salmonella sp* (most common cause), *Staphylococcus aureus*, *Vibrio sp*, *E. coli*, *Yersiniaenteroclitica* and Norwalk-like virus as the important microbial pathogens responsible for foodborne illnesses in India.

[6] Source: National Dairy Development Board

Potential Sources of Food Safety Hazards In Food Supply Chains

Agricultural inputs	Farming	Storage/ Transport	Processing	Retailing	Consumer
Seed borne diseases	Contaminated water and soils	Improper drying, storage, pest control	Cross contamination with pathogens	Improper handling & packaging	Cross-contamination
Use of banned pesticides	Improper pesticide use	Unhygienic handling and transport	Lack of/ abuse of process controls	Unhygienic transport	Poor sanitation
Irrigation water	Improper animal health practices	Poor sanitation	Use of unapproved food additives	Improper storage, temperature abuse	Improper storage, temperature abuse
Heavy metals		Chemical contaminants like unapproved preservatives	Heavy metals	Poor sanitation	
Manure			Contaminated Water		
Animal borne diseases			Poor sanitation		

The Way Forward

- Adoption of an integrated approach to food safety throughout the food chain "from farm to fork" is critical for preventing food borne diseases and other food safety hazards.
- Good Agricultural Practices (GAPs), Good Hygiene Practices (GHPs) and Good Manufacturing Practices (GMPs) lay the foundation for food safety system.
- Networking of laboratories that are involved in identifying food safety challenges with regard to pathogen detection, residue (pesticides, hormones, antibiotics) analysis and identifying fraudulent practices such as adulteration/ preservatives in foods.
- Preventive approaches such as the Hazard Analysis Critical Control Point System (HACCP), have resulted in industry taking greater responsibility for control of food safety risks and this needs to be further enhanced.

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Indian Federation of Animal Health Companies popularly known as INFAH is the united progressive force of companies & non-profit organizations working towards animal health care. It is an organization formed under section 25 of Indian Companies Act. INFAH heads strong with 47 member companies belonging to different genres of animal husbandry industry of India right from feed manufacturers, medical support systems to researchers.

INFAH is created to promote ethical practices and enhance Animal health Industry's value and contribution in the society. INFAH also offers a dynamic platform to create awareness about controlling diseases, provide effective treatments and improve overall productivity of animals.

The changing economic and climatic scenarios globally is fostering many hazards to livestock, poultry, aqua & companion animals which needs to be addressed more effectively and efficiently by veterinary professionals and animal health product manufacturers/distributors. We at INFAH collaborates these concerns across the industry & work towards enduring solutions with collective approach by experts. This larger picture helps all members with a better understanding of Animal Health and encourages a scientific approach that facilitates the supply of innovative, cost effective and quality products & services.

At the global stage, INFAH is partnering with Global Animal Trade Bodies and creating strong impressions for the Indian Animal Husbandry and Animal Health Industry. INFAH is affiliated by International Federation of Animal Health Companies i.e. IFAH.

Address: 311, Mastermind IV, I.T. Park, Royal Palm Estate, Aarey Colony, Goregaon (E), Mumbai - 400064. India.

Phone: +91 (22) 2876 1515; **Email**: info@infah.org

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Sathguru Management Consultants

India Office
Plot 54, Sagar Society, Road No.2,Banjara Hills, Hyderabad - 500034
Email: info@sathguru.com | www.sathguru.com
Tel : +91 40 6627 6200 | Fax : +91 40 4004 0554

US Office
93 Shennecossett Road, Office 150, Groton, CT 06340
M : +1 617 338 2777 | F : +1 617 812 0263

Indian Federation of Animal Health Companies
311, Mastermind IV, I.T. Park,Royal Palm Estate, Aarey Colony,
Goregaon (E), Mumbai - 400064
E-mail: info@infah.org | www.infah.org