

# THE NEED FOR RESEARCH AND DEVELOPMENT OF VETERINARY ANTI-BACTERIALS

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# What is IFAH?



- Global body representing companies engaged in the research, development, manufacture and commercialization of animal health products in both developed and developing countries across the five continents.
- IFAH's members include animal health companies and national/regional animal health associations. In turn, these associations represent a broad range of concerns, from small, local businesses to international enterprises. Together, these companies supply approximately 80% of all animal health products used worldwide.
- IFAH is an international non-profit organization, registered under Belgian law, and based in Brussels.
- More information: [www.ifahsec.org](http://www.ifahsec.org)

# IFAH's Mission



- To foster a greater understanding of animal health, and to promote a predictable, science-based regulatory environment that facilitates the supply of innovative, quality products into a competitive market place. These products contribute to the supply of safe, healthy food, and to high standards of health and welfare for animals and people.

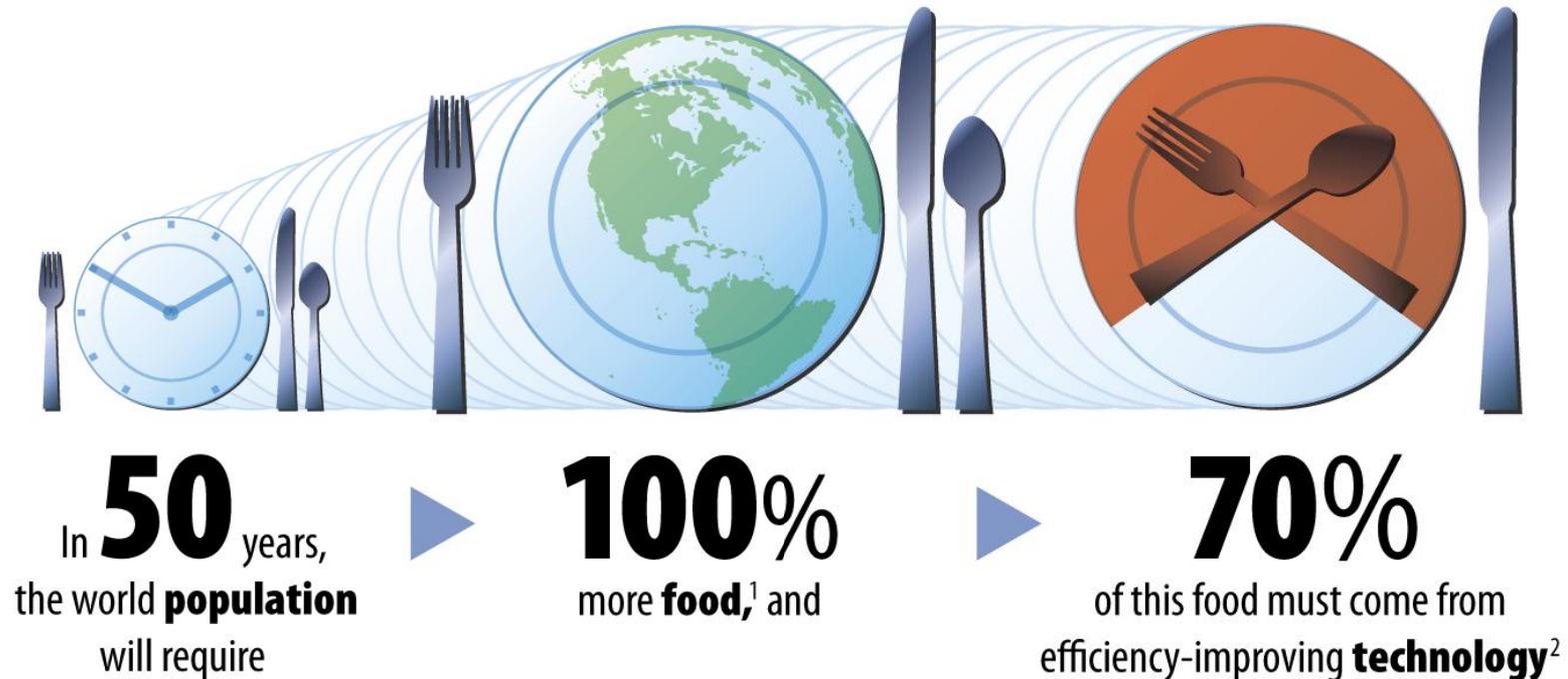
# Outline

- Need for Antibiotics
- How Antibiotics are Discovered, Developed, Marketed and Used
- Factors Shaping the Antibiotic Pipeline
- What does the future hold for new veterinary anti-infectives?

# Food Economics and Consumer Choice

## An overview of the challenge ahead

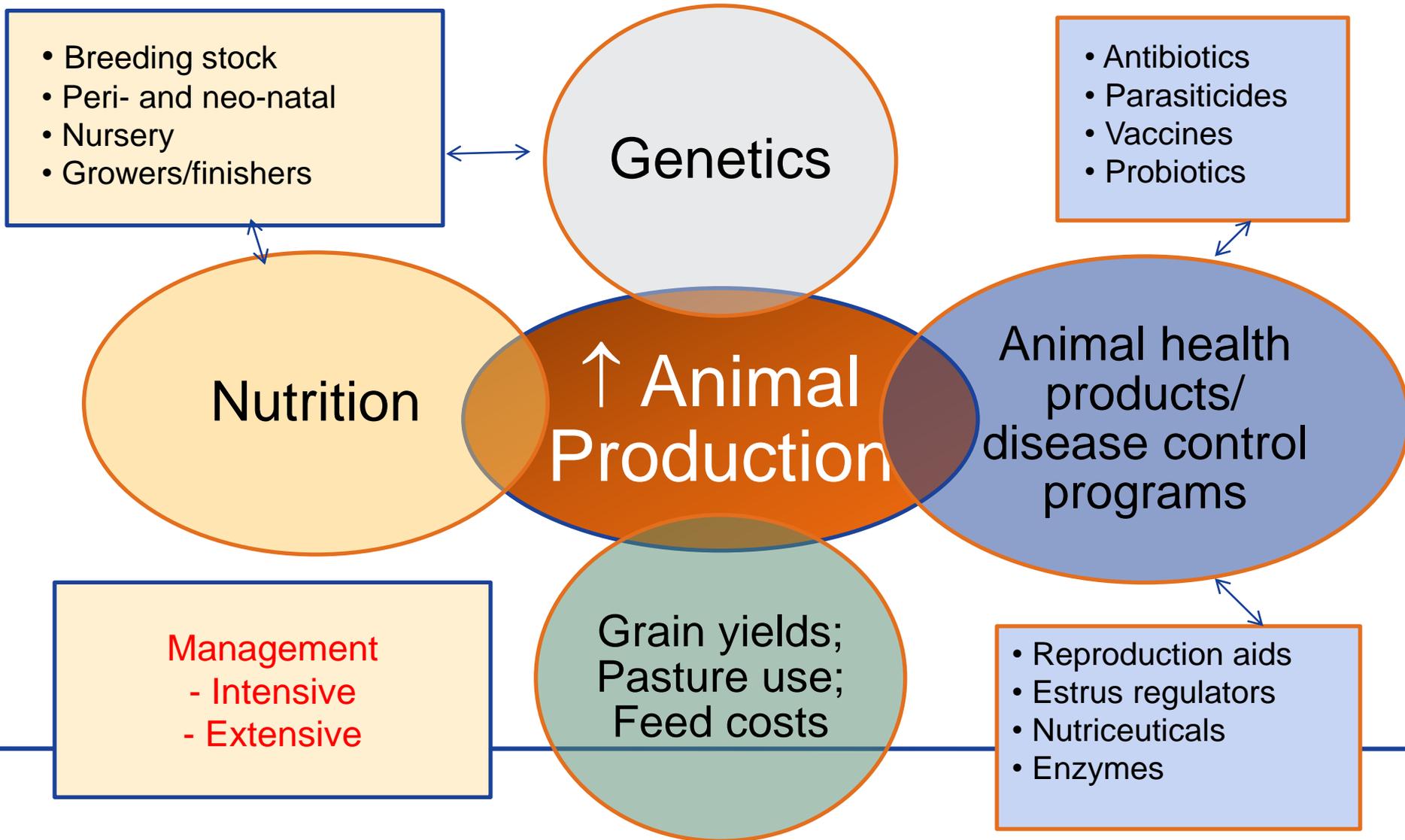
### Key Data



1 Green, R. et al. January 2005. "Farming and the Fate of Wild Nature." Science 307.5709: 550-555; and Tilman, D. et al. August 2002. "Agricultural sustainability and intensive production practices." Nature 418.6898: 671-677.

2 "World Agriculture: toward 2015/2030." 2002. United Nations Food and Agriculture Organization, Rome. Accessed 12/8/08. <<ftp://ftp.fao.org/docrep/fao/004/y3557e/y3557e.pdf>>.

# Factors in Livestock Production Efficiencies



# Animals Get Sick Like People

- Regardless of the production system
  - Regardless of the level of management
  - Regardless of the species
  - Regardless of the geographical location
  
  - Therefore, animals [will always] need infectious disease treatment and prevention
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# Controlling infectious disease: the toolkit

- Management: housing, nutrition, “all in:all out, all clean in between”
  - Biosecurity (shower in/shower out, traffic flow on/off farm, closed herds)
  - Vaccines
    - Viral: but viruses mutate and change
    - Bacterial: especially the challenges with bacterial vaccines
      - Efficacy is variable, limited for some infections, injection site reactions, modified live vs. killed vaccines
  - Probiotics/direct fed microbials
  - Treatment of bacterial infections
  - Natural Products (oils, plants, minerals, etc.)
    - Unproven
    - Unintended consequences (eg, environmental, palatability, etc.)
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# Disease control: The Innovation Paradox

- Animals will continue to get sick, even with optimal use of the tools in the kit
- Antibiotics and vaccines are product categories where constant updates and innovations are indispensable
- Responsibly developing new antibiotics and alternatives to antimicrobials is important to both human and animal health and the regulatory pathway needs to remain predictable, transparent and science based
- Otherwise, industry will invest R&D in other areas with the consequence that veterinarians will have even fewer treatment options available in the future – jeopardizing our one health

## Developing Novel Products

- Commercial accessibility of novel compounds depends on
  - Successful new molecule/antigen discovery
  - Advancement of the drug candidate through safety and clinical development
  - Formulation and chemistry
  - Validation of a commercial-scale manufacturing process
  - Efficient regulatory review and final approval by the regulatory agency
  - Timely access to the market to meet the needs



# Human and Animal Health R&D Processes

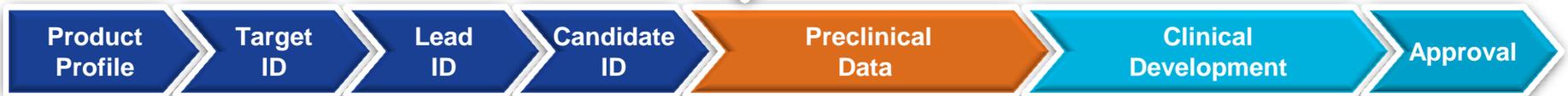


↑ **First in Man Studies**  
(Requires IND or Equivalent)

12–15 years  
0.5–1.0B Euros

**Human Health Discovery**

↓ **First Target Animal Studies**  
(Does not require INAD)



8–12 years  
80–100M Euros

**Animal Health Discovery**

# Initiating the Discovery Process – Beginning with the end in mind

## Begins with a Target Profile

- Label Claim (treatment of X disease caused by X organisms)
- Market differentiators (single dose, oral, etc.)
  - Requires knowledge of current and future market conditions
- Market value

## Key Points

- Investment is made at risk
- Assumes a defined regulatory process for that class of agent
- Timeline for process is 10 – 15 for HH and 8–12 years for AH

# Past and Future Sources of AH AB Substrate

2000s – HH and AH targets have diverged

1980s

- Fluoroquinolones
- 3<sup>rd</sup> Gen Ceph
- Florfenicol

1990s

- 4<sup>th</sup> Gen Ceph
- Novel Macrolides

Human Health Programs

- MRSA
- MDR Pneumococci
- MDR Gram-Negatives
- MDR TB

Animal Health Programs

- Livestock
  - Respiratory Disease
  - Enteric Disease
- Companion Animals
  - SSTI
  - UTIs

This severely limits the ability of AH to leverage substrate!

# The Next Generation of Animal Health Anti-Infectives will need Unique Substrate

- Animal Health Anti-Infective Programs will need to discover novel anti-infectives that meet the veterinarians needs for animal welfare while minimizing impact on human health
  - Not Narrow or broad spectrum but “Veterinary Specific Spectrum”
  - Exploits all available substrate
- Traditional Small Molecules
  - Novel Classes
    - May exploit an existing target or novel target
    - AH may be able to utilize compounds discarded by HH programs due to delivery or safety issues that are not of concern in AH
  - Re-exploration of older generations of existing classes
    - Initiate chemistry program to develop novel analogs within an older class
- Non-Traditional Substrate (“Alternatives to Antibiotics”)
  - Antimicrobial Peptides
  - Bacteriophages (Phage Lysin Constructs)
  - Current regulatory position is that these will be regulated using same pathways as traditional agents
    - Time to market is not likely to be shorter than traditional small molecules
    - Regulatory flexibility will be needed.

## Intellectual Property Protection

- Patent lifecycle is critical to return on R&D investment
- Recouping investment more difficult for smaller market products of animal health
- Maximization of IP protection hinges on efficient development, predictable regulatory review, and expedient access to the market



# What can policymakers do to foster innovation?

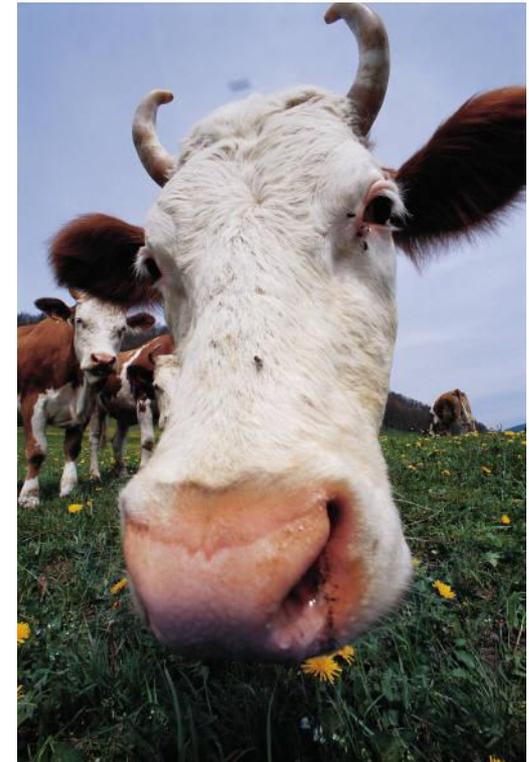
**Recognize the need for innovation**

**Inform and educate consumers about value of innovation**

**Embrace innovation – the status quo will lead to undesirable outcomes**

**Streamline approval process: predictable, science-based regulation**

**Extend exclusivity – payback on investment**



**Think long-term ... act with urgency**