

International Bar Association 2023 Annual Conference

Agriculture and Food Section

**Antimicrobial Resistance Regulation in the
Context of One Health: How Legislation Can Help Reduce AMR**

By

Lynn L. Bergeson and L. Claire Hansen

On October 31, 2023, the Agriculture and Food Section (AFS) of the International Bar Association (IBA) presented a panel discussion at the IBA 2023 Annual Conference in Paris, France, on [antimicrobial resistance \(AMR\) regulation in the context of one health: how legislation can help reduce AMR](#). Lynn L. Bergeson, Managing Partner, Bergeson & Campbell, P.C. (B&C[®]) and AFS Chair, co-chaired the session with Anderson Ribeiro, Partner, Souto Correa Advogados, who also moderated the panel discussion. Presenters included Philippe Becquet, Independent Expert Consultant, International Feed Industry Federation (IFIF), an agronomist specializing in animal nutrition; Gilles Boin, Partner, Qolumn Law, with expertise in French and European products law; and Carmen Bullón Caro, Legal Officer, Food and Agriculture Organization of the United Nations (FAO) -- Development Law Service (LEGN), an internationally recognized AMR expert. The session was co-sponsored by the Healthcare and Life Sciences Law Committee and the Technology Law Committee.

Bergeson introduced the topic by noting that the World Health Organization (WHO) and the European Union (EU) have identified AMR as a top global health concern. The costs to society of failing to address AMR are staggering and increasing globally. One of the reasons the AFS organized this panel was to generate greater visibility of this global threat and emphasize just how important it is from a public health perspective. The issue is complicated, and necessarily addressed differently by developing economies versus more developed countries. Strategies intended to address this threat globally must calibrate responses accordingly.

Session moderator Ribeiro noted that AMR is not new and that scientists and regulators have been aware of AMR for decades. The discussion has been at times relegated to the human health space, where focus has been on the misuse or overuse of antimicrobials. We are becoming increasingly aware, however, that the issue is far more complex and of the utility of the One Health approach. The pandemic was a major driver of awareness of this issue, recognition of the number of pathogens of which we are newly aware, and how great a threat these pathogens are to human health and the environment.

The intersection of human health, animal health, and environmental health is at the heart of One Health, and any approach to address AMR must be holistic and consider all elements of the problem. The One Health approach began in the 1970s. Increasingly, however, decision

makers and other stakeholders are considering legal instruments -- treaties, laws, and regulations -- to effectuate solutions to AMR.

Panelist Opening Remarks

Bullón focuses primarily on animal health and plant health in her role as legal advisor at FAO. FAO has been working on AMR for decades, but this issue has been especially urgent since 2015. The One Health approach has been especially relevant in FAO's dealings with AMR. It is an intersectional issue from animal law, waste management, pesticides, environmental law, and related aspects. Bullón noted that FAO will release on November 28, 2023, its toolkit, One Health Legislative Assessment Tool for Antimicrobial Resistance. The One Health Quadripartite Collaboration reflects the efforts of the United Nations (UN) Environment Programme (UNEP), FAO, WHO, and the World Organization for Animal Health (WOAH). The FAO document will outline its strategy for reducing AMR and reliance and will offer helpful legislative assessment tools for stakeholders.

Boin introduced himself as a food and product lawyer. His approach to AMR is driven by issues and questions that he fields from his clients. Boin noted the challenges to finding a solution that is both scientifically grounded and sufficiently flexible to reflect the legal nuances of the jurisdiction assessing potential solutions.

Becquet noted that as a non-lawyer scientist, his perspective is understandably different from those of the other panelists. He introduced IFIF as a global organization that represents over 80% of animal feed production worldwide. "IFIF's vision is to provide a unified voice and leadership to represent and promote the global feed industry as an essential participant in the food chain that provides sustainable, safe, nutritious and affordable food for a growing world population." Feed components are very much a part of the solution. Feed is not just the food itself, but also the nutritional additives that are part of feed. IFIF works to reduce the introduction and spread of microorganisms between farms. Having an adequate definition of "nutrition" is important. One of the most important conflicts that we have is with our gut, with acting on the microbiome. We want the food to provide the correct nutrition, but also to support animals to address environmental stressors. The form food takes is hugely significant and impacts the animal gut and health.

Questions to Panelists

Q: What is the One Health Concept, and how can we take this approach into consideration so it can work legislatively across sectors?

Bullón responded first. A One Health approach will require coordinated implementation across different sectors, requiring a mechanism across government sectors that is efficient. This requires a legal architecture that is sector-specific but benefits from a broader legislative underpinning. Sometimes these laws have different principles, are regulated by different governments, and pose significant implementation challenges. The concept of One Health focuses on the intersection of animals, humans, and the environment. There is a need for sectors to work together to create a synergistic approach encompassing governance and governing legislation.

Boin noted that One Health is a holistic approach to AMR. We want to reduce our reliance on antibiotics to increase their efficacy. The United States has created some useful documents on this topic, and Boin noted that AMR will have huge economic and health consequence by 2050. To address AMR, we must cut across these disparate sectors. As antimicrobials enter wastewaters, there are implications for all health sectors. It is a big challenge for regulators. It requires acting at many different and challenging points.

With regard to the United States, we note that on September 26, 2023, the U.S. Environmental Protection Agency (EPA) [requested comment](#) on a proposed framework to strengthen the assessment of AMR risks associated with pesticide use. EPA, the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Agriculture (USDA), under the oversight of the White House Executive Office of the President, have published a [concept note](#). EPA states that the concept note is the first step in creating the framework to improve assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in AMR that compromises the effectiveness of medically important antibacterial and antifungal drugs. EPA states that the proposed framework described in the concept note will expand EPA's current process for assessing the risk that antibacterial or antifungal pesticides may pose to the effectiveness of human and animal antibacterial and antifungal drugs when EPA evaluates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the U.S. law regulating pesticides.

Becquet noted, as did Boin, that everything is related and interacts. The best antimicrobial is the one that is not used. When humans or animals are sick, that is the time to administer antibiotics. Good nutrition for humans and animals is key, since healthy populations also reduce reliance on AMR.

Q: What has been done at the international level to reduce the regulatory gap and address the One Health approach?

Bullón noted that 2015 was a landmark year because of the implementation of the One Health Legislative Assessment Tool for AMR. This methodology is divided into multiple chapters. FAO has been working with WHO on a One Health approach that will be released later in November 2023, as noted. The document to be released is an assessment tool, meaning that FAO is not creating guidance, but rather compiling existing guidance to make it available to stakeholders. FAO wishes countries to develop comprehensive AMR policies. Finding the right balance between legislation and other approaches is challenging.

Q: What has been implemented at the regional level in Europe, and how are we managing to progress across sectors?

Boin noted that the EU AMR action plan was created in 2001. It focused mainly on animal health and on enhanced communication to provide clarity and direction for its policy actions. The next step was another action plan to combat AMR released in 2011. It was the first time that the One Health approach was used, but it did not thoroughly incorporate the environment. The third step was in 2017, when a holistic approach that uses the One Health approach was firmly adopted. The EU is still using this approach. There have been many developments since the

pandemic, and momentum has been building to step up EU action plans. All three EU governing bodies (the EU Parliament, the Council of the EU, and the European Commission (EC)) have adopted stronger language to address AMR. There are requirements to adapt the EU AMR action plan to do more in the next few years. Animal health is the most advanced area. The veterinary medicine regulations are among the strongest, followed by human medicine. A key hot topic is whether antimicrobials should only be prescribed by doctors. The last aspect is the environment, because the EU recognizes that many data are missing to make data assessments on AMR in the environment.

Q: How can industry contribute to the One Health approach to engage in better forms of self-regulation, so they do not rely solely on government regulation?

Becquet noted that it is not realistic to rely solely on government regulation. In the most developed countries, the impact of antimicrobial growth promoters (AGP) is minimal. But if you go to farms where basic hygienic systems are not in place, loss is much higher -- 7-8 percent. We need to make sure that all hygienic elements are in place before we begin to remove AGPs. The feed industry is working on this with FAO.

According to Boin, a key element is to change the system. This is, of course, challenging to do regulatorily. When it comes to antimicrobials, it requires educating stakeholders about the use of antimicrobials in human and animal medicines, but we need to go further to medical users at all steps (patients, farmers, and beyond). Good hygiene practices within the farm also need to adhere to strong prevention plans. Unless there is strong participation in these measures, effectuating change will be hard.

Bullón noted that it is important to facilitate conversations between governments and industry stakeholders to co-create regulation. This will better ensure implementing the most suitable legislation designed to regulate these different sectors. Bullón noted that it is important to ensure that antibiotic quality is maintained; otherwise, antibiotics will not be effective.

Q: Sometimes there is cultural and iconic resistance to implement these regulations at the local level. How much resistance do you feel from some specific countries, and how much does this interfere in the global markets?

Bullón noted the difficulty of implementation. There will be dire impacts on human health if environmental measures are ignored. We cannot let environmental regulations slide or go unenforced; they must be implemented effectively.

Becquet responded that not all wish to implement what we see as the solution to AMR, particularly in the production of animals. Changing animal care programs is easy. For countries only first developing these structures, however, it is a more demanding proposition. We need to make sure that basic health practices and policies are in place. We have looked at countries that could improve, and we have looked at countries that have limited outside interference on their animal production systems. It is necessary to consider both models; otherwise, they will not work.

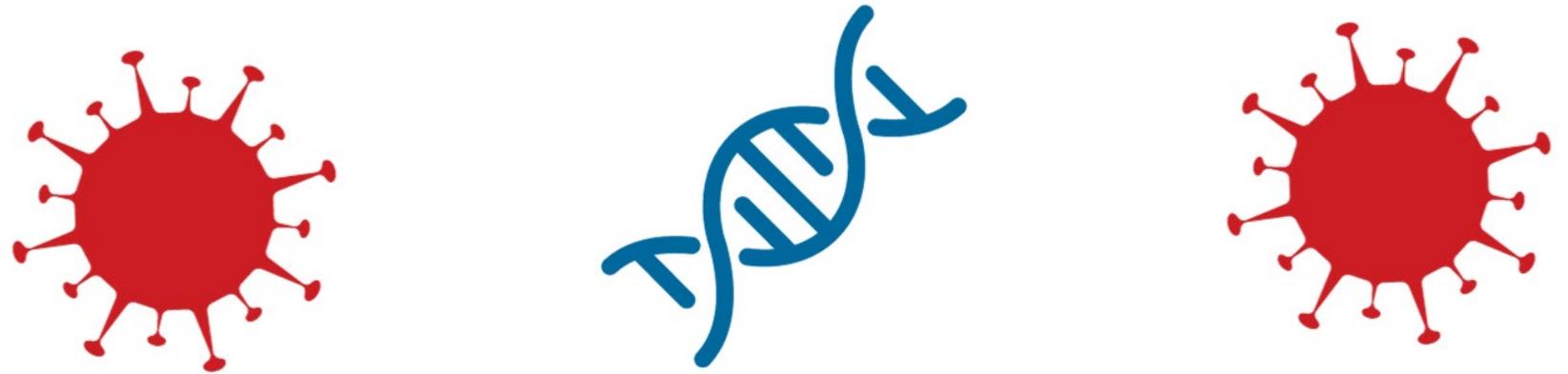
Bullón added the importance of focusing on prevention. Prevention is the best way to reduce reliance on antimicrobial intervention.

Q: Are there any specific goals or good examples of practices that we aren't using as much as we could? Is there a one-size solution that we are missing?

Boin responded no, not really. There is educational work, financing work, and setting objectives for reducing AMR. There are measures in animal medicine, but not human medicine. We need to collect data to know exactly where the problem is, set objectives, and step up adopting regulatory requirements.

The slides used at the discussion are appended.

Antimicrobial resistance regulation in the context of one health: how legislation can help reduce AMR



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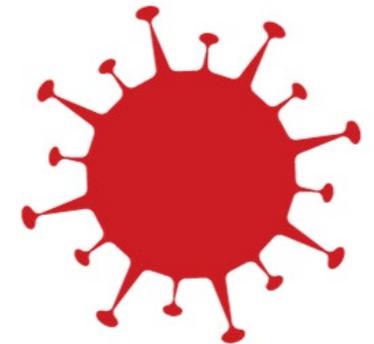
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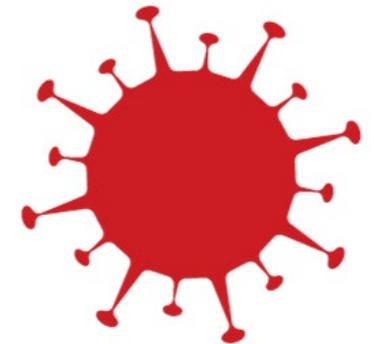
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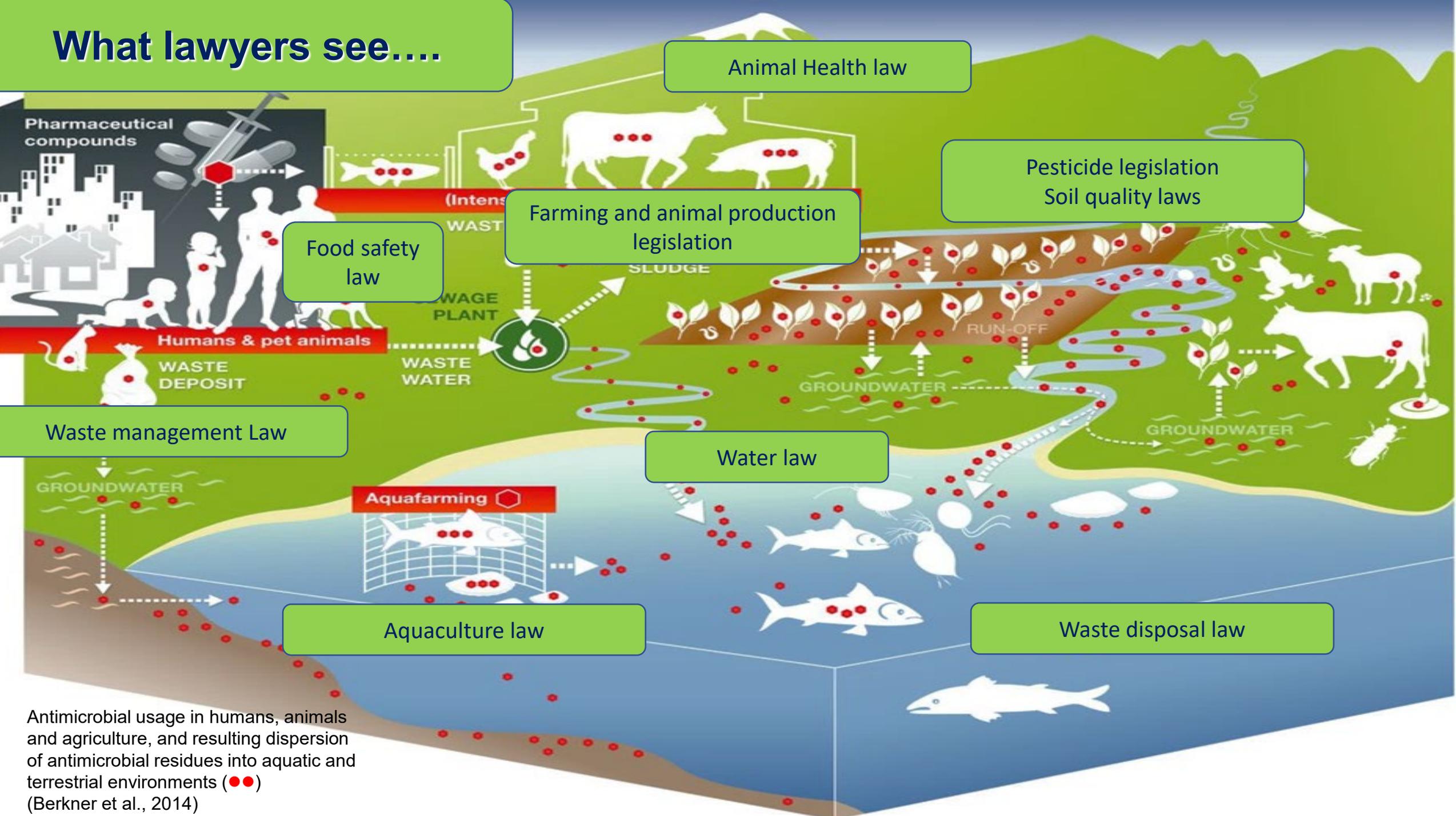
One Health Legislative Assessment Tool for AMR

MPTF Global Legal Project

ONE HEALTH QUADRIPARTITE COLLABORATION



What lawyers see....



Animal Health law

Pesticide legislation
Soil quality laws

Farming and animal production
legislation

Food safety
law

Waste management Law

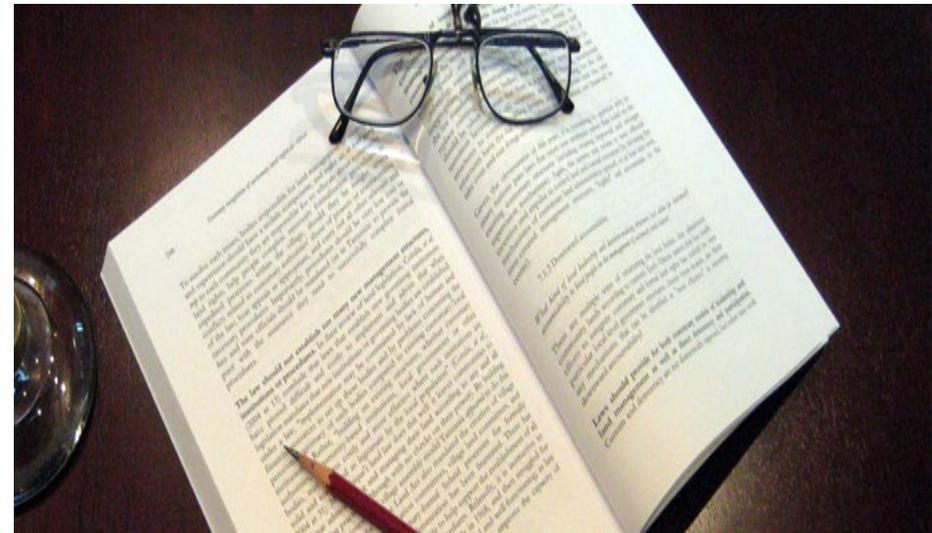
Water law

Aquaculture law

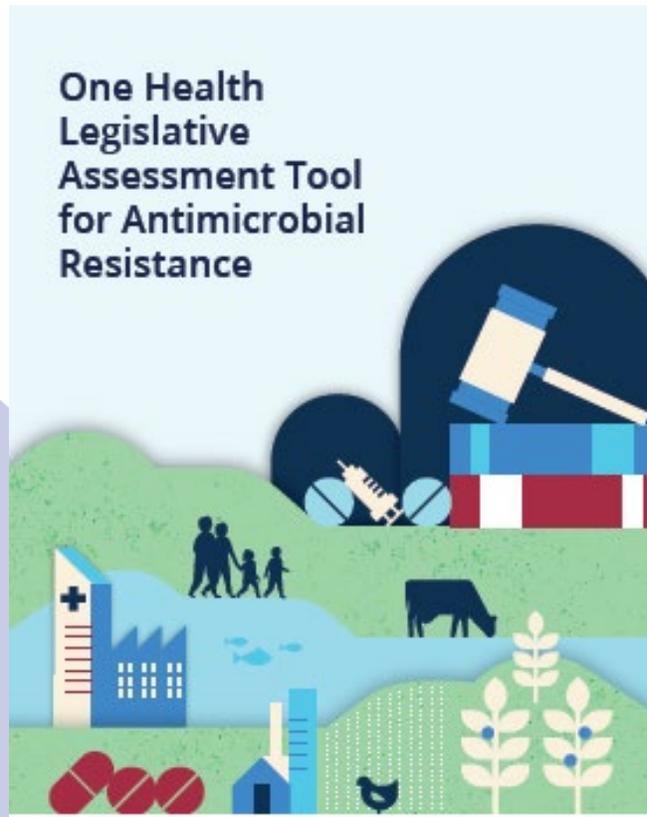
Waste disposal law

Antimicrobial usage in humans, animals and agriculture, and resulting dispersion of antimicrobial residues into aquatic and terrestrial environments (●●)
(Berkner et al., 2014)

Development and Piloting of a One Health Legislative Assessment Tool for AMR

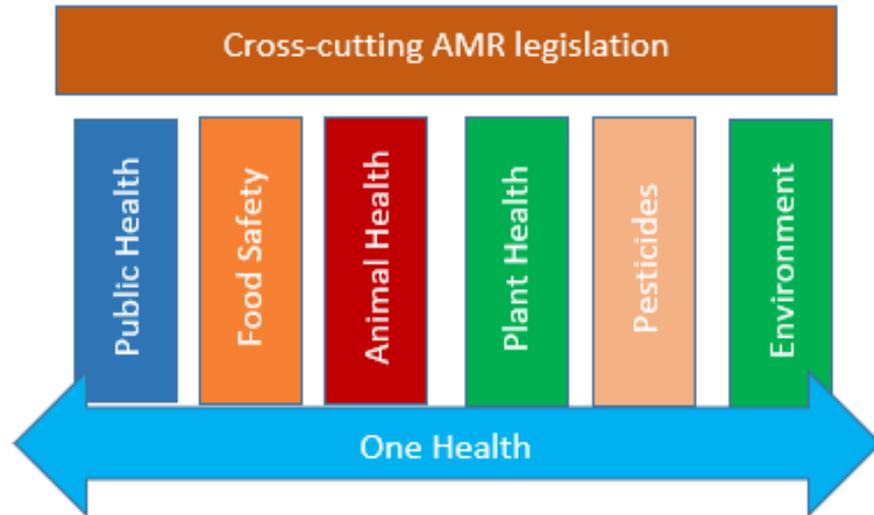


One Health Legislative Assessment Tool for Antimicrobial Resistance



Launching of the Tool: November 2023

Conclusions



- A legal architecture to address AMR requires a combination of sector-specific and cross sectoral legal responses
- Cross-sectoral legal responses need multiple institutions to be implemented.

This can be useful to:

- Set up an integrated AMR governance mechanism
 - Declare AMR of common interest
 - Provide a legal basis to integrated surveillance
 - Secure a budget allocation for AMR
 - Introduce a general obligation to keep and share data
- Cross sectoral legislation should not introduce sector specific elements, as that would lead to **legal fragmentation.**

Thank you!



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IFIF's Vision

One global voice for our industry

“IFIF’s vision is to provide a unified voice and leadership to represent and promote the global feed industry as an essential participant in the food chain that provides sustainable, safe, nutritious and affordable food for a growing world population.”

IFIF is a global organization that represents over 80% of animal feed production worldwide

National and Regional Associations



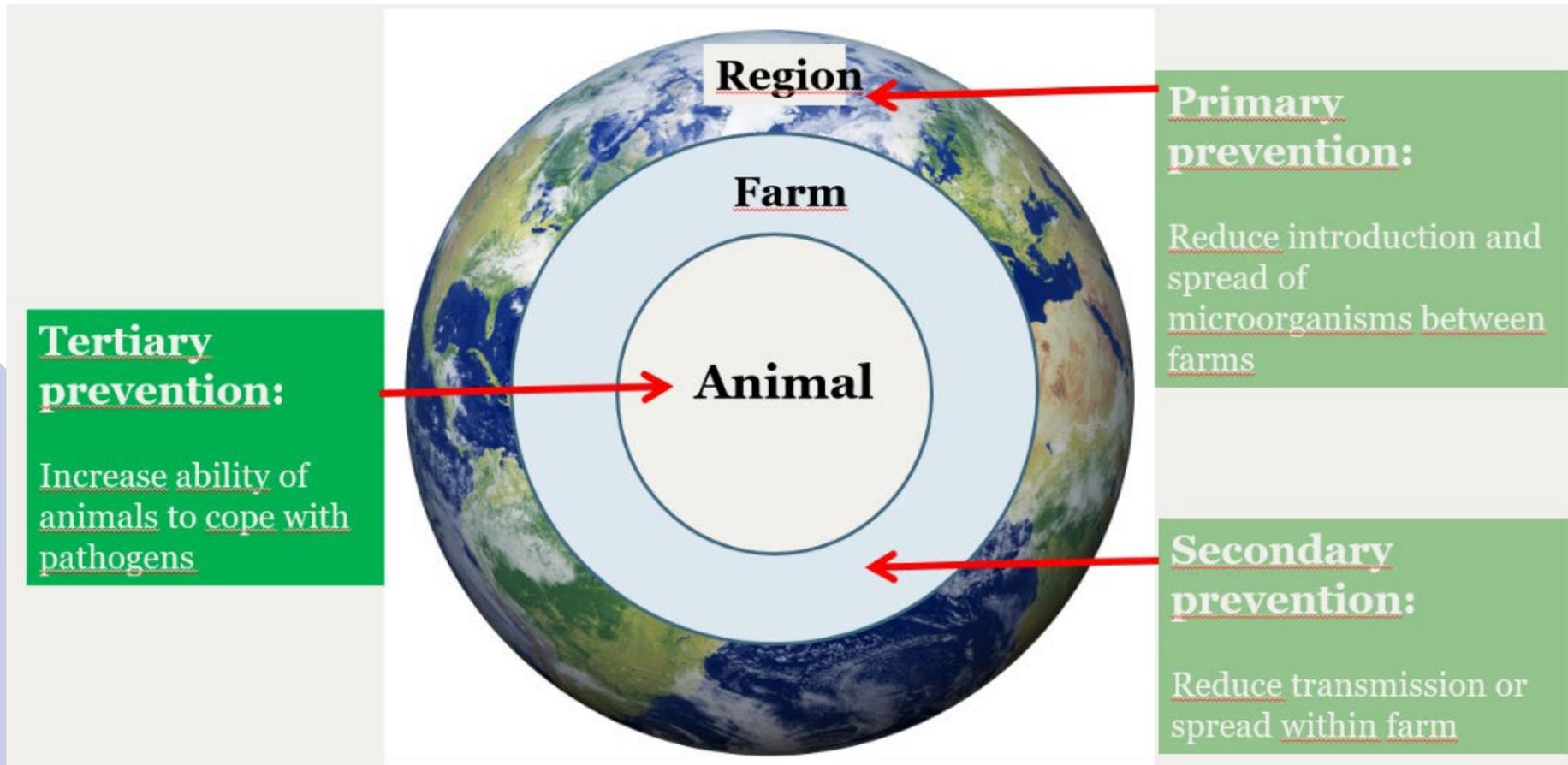
Corporate Members



Feed-related Organisations

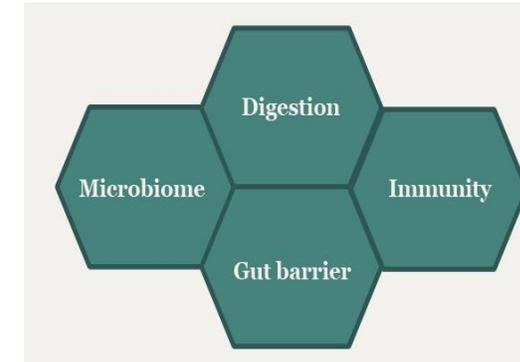
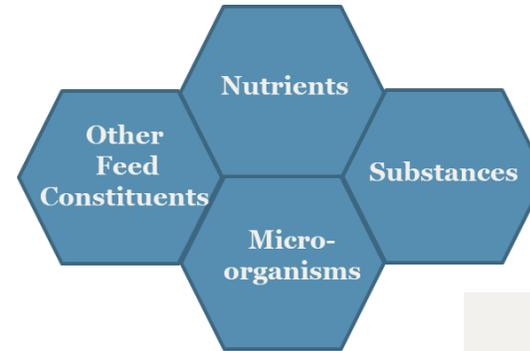


Tertiary Prevention

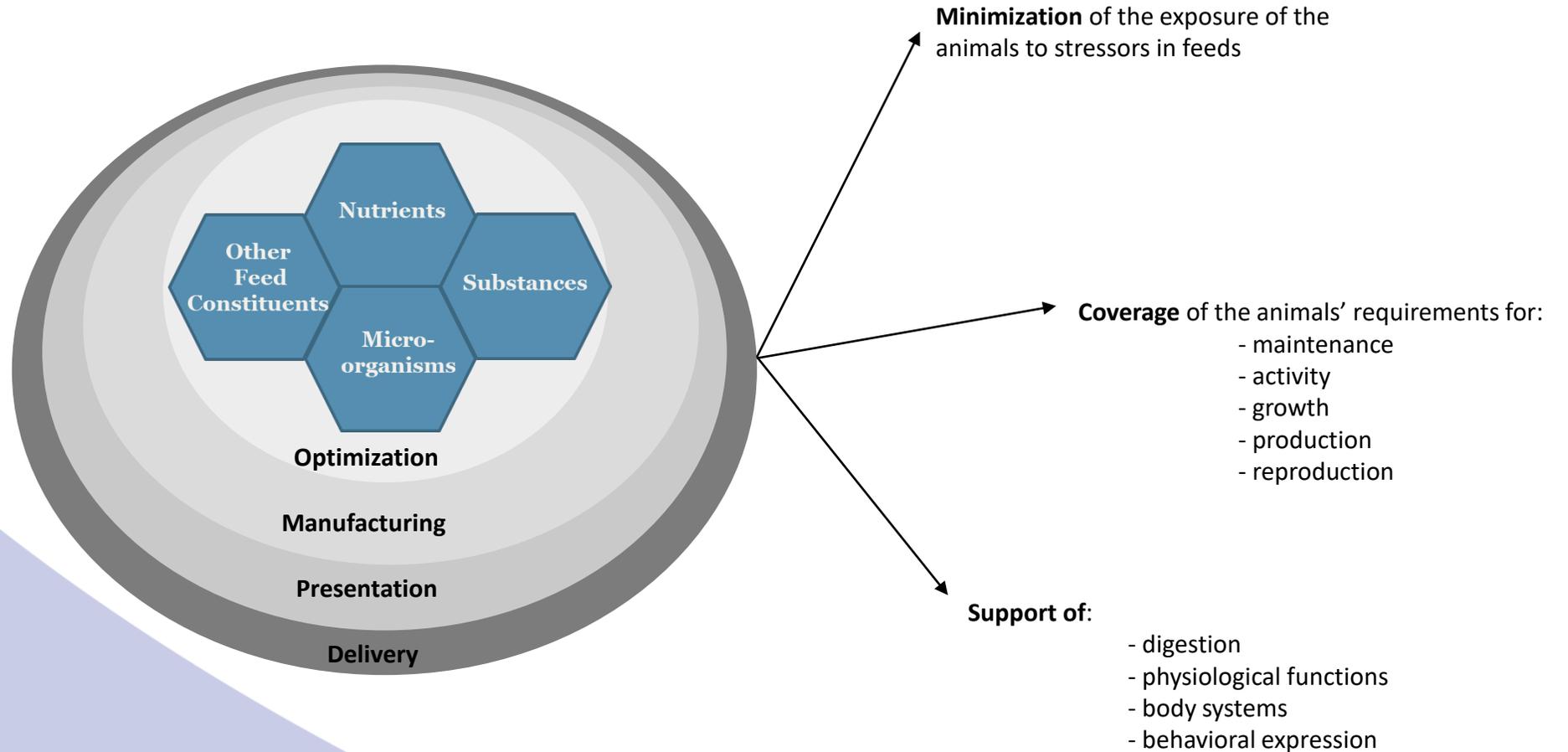


Adequate Nutrition Definition

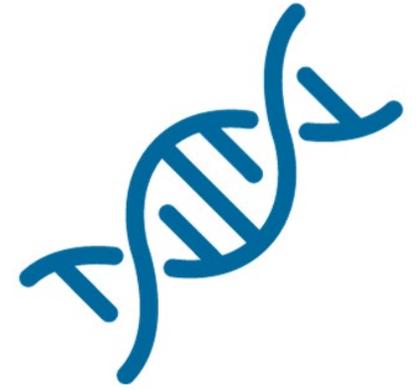
- **Oral Intake of adequate levels of:**
 - **Nutrients**
 - **Substances**
 - **Microorganisms**
 - **Other feed constituents**
- Considering their:
 - **Combination**
 - **Presentation**
- Necessary to **fulfill functions** related to:
 - Their **physiological states**
 - Including the **expression of most normal behavior**
 - And their **resilience capabilities** to cope with stressors of various types encountered in appropriate husbandry conditions



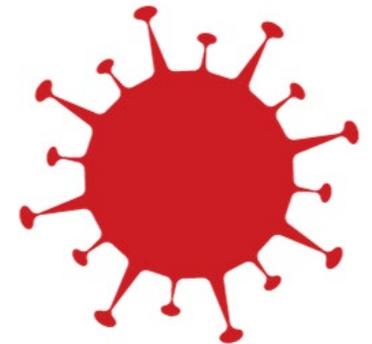
Adequate nutrition is achieved through the:



Antimicrobial resistance regulation
in the context of one health:
how legislation can help reduce AMR



Q&A



You are invited to join the Agriculture and Food Section (AFS)

Agricultural law covers a comprehensive and dynamic legal practice area, in particular relating to:

(i)
Agriculture land
usage, ownership,
and farmers' rights

(ii)
Seed law, plant
variety law,
biotechnology/
GMO law

(iii)
Food trade, food
safety, and food
liability

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- *Resources* -- www.lawbc.com/uploads/docs/00373969.pdf

Responsible Land-Based Investments in Agriculture: Asia-Pacific Focus

- *Recording* -- www.ibanet.org/conference-details/CONF2216
- *Resources* -- www.lawbc.com/uploads/docs/00373970.pdf

Responsible Land-Based Investments in Agriculture: Latin America Focus

- *Recording* -- www.ibanet.org/conference-details/CONF2415



Background

- In the past decade some investors achieved significant returns on land-based investments in agriculture and forestry in developing countries.
- Some benefited the countries and communities, too.
- Not all land-based investments are equally beneficial, and those that harm communities, workers and the environment create great risk to the success of the investment.
- Evidence that investors who fail to use responsible investment practices incur much higher costs and thus a reduced likelihood of receiving a reasonable risk-based return on the investment.
- Here we will discuss how lawyers can help clients manage these risks.

Take Aways

- Governments have binding international legal obligations to ensure meaningful consultation and, where relevant, FPIC
- Focus should be on communities accessing information, participating, and influencing decision-making
- Need to recognise, respect and protect all legitimate tenure rights

END!!!

THANK YOU

IBA Agriculture and Food Section

