

ANTIMICROBIAL RESISTANCE AND THE TPP

Supplementary Information on evidence provided by Anna George to JSCOT Request for information on AMR and policy prescriptions relevant to the TPP

Primarily my concern is for Australia's trade policies to be calibrated and sensitised to ensure unintended consequences from the TPP's regulatory coherence, harmonisation and trade facilitation measures do not inadvertently undermine Australia's capacity to regulate for AMR.¹ This approach is also consistent with the view ² expressed in JSCOT Report 154, which recommended ratifying the Australia/China FTA.

"The Committee has been alerted to the dangers presented to the health security of Australians by antimicrobial resistance. The Committee recognises the link between microbial resistance and Australia's current regulatory framework which enables Australia to control antibiotic use. The Committee is aware that this regulatory framework must not be threatened by Australia's commitments under FTAs and will be monitoring this area during its examination of future agreements." (Para 6.29)

I have specifically focused on measures to address AMR in food, particularly the global food supply chain - that the TPP is claimed to facilitate - but recognise AMR issues are much larger and more complex.

1. Trade policy and negotiations should be re-calibrated to ensure priorities are consistent with Australia's AMR health security objectives. The trade objective to preserve and enhance Australia's reputation for producing safe, clean food should be augmented to include food free of AMR risk – also a global health security priority.
2. Promote global and domestic trade policy frameworks to ensure antibiotic use is reduced: Antibiotics designated for humans should not be used in food production (implement WHO Guidelines). Antibiotic use in food production should be limited to justifiable and monitored therapeutic use only (implement FAO and OIE Guidelines).
3. Establish National Treatment Provisions so that Australia can implement effective AMR testing of both domestic and imported food products; and, work to ensure that CODEX standards are compatible with Australian and global health security priorities.

Australia currently does not systematically test at the border for AMR in the food chain nor is systematic testing applied to domestic production. AMR is only tested on an ad hoc basis (Fed, State some industry and research/academic projects) nor is reporting of AMR events in the community comprehensively addressed).

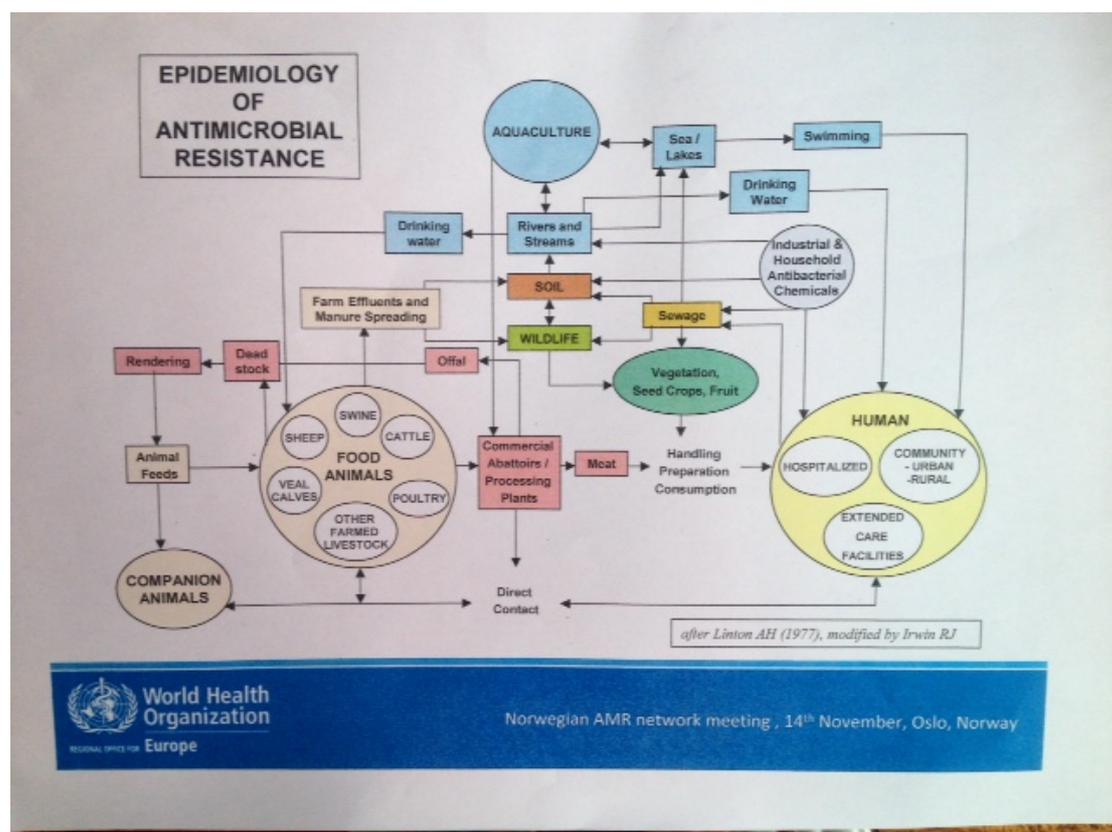
Our existing trading rules address food safety but with levels of AMR growing new approaches are required. Food contaminated with bacteria and fungus may now also contain AMR. This form of foodborne AMR transmission is more life threatening especially with key antibiotics become impotent. Also AMR through the food chain can enter the gut and change bacteria in our bodies.³ Health security must therefore be prioritised over trade rules and procedures. The information provided below is to clarify some points raised:

¹ Australia's AMR policy strategies can be located at the Health Dept. website:
<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-amr.htm>

² http://www.aph.gov.au/Parliamentary_Business/Committees/Joint/Treaties/17_June_2015/Report_154

³ <https://theconversation.com/we-know-why-bacteria-become-resistant-to-antibiotics-but-how-does-this-actually-happen-59891> Provides a good non-expert explanation of how AMR develops.

Why should AMR be given exceptional treatment over trade rules designed to address food contamination or other chemicals or pesticide residues contained in traded food or other processed materials? The answer to this lies in the complex web of antibiotic use in food production detailed below and the consequences of misusing such important drugs. The chart below shows trail of behaviour that leads to the transmission of AMR into the global food chain and internationally.



The following is provided for background and context for the policy proposals outlined above. Also included are links to substantiating documents provided in response to a request for information from the Committee.

A world without effective antibiotics is unimaginable but is now a global health security threat: Antibiotics fundamentally transformed health outcomes and without them medicine will return to the 'dark ages' where an infected scratch could result in sepsis and death. The failure to consider antibiotics unique contribution to national and global public health and food security now has to be addressed, urgently: A global consensus is beginning to emerge that 'business as usual' is not an option - that antibiotics should assume the status of a public good and new antibiotics not enter the open market in the same manner. These developments will impact on international trade, particularly the global food supply chain.

AMR cannot be eliminated only managed: Food contaminated with bacteria generally has an immediate effect on individuals, is measurable and eventually containable and trade rules include measures to address it. But the health risk from bacteria is now fundamentally altered: bacterial containing AMR affects communities - local and global - directly and indirectly. AMR as well as altering bacteria through genetic mutation, AMR can also morph through horizontal transfer to affect other bacterial - further undermining the efficacy of antibiotics;⁴ AMR can be transmitted to other species, from animals to humans and vice versa; and AMR can be transferred through food, agricultural and aquaculture products, through soil, water, industrial waste, sewage and to wildlife and the environment.⁵

AMR is not a transient problem: AMR transmission cannot be stopped it can only be carefully managed by substantially reducing the use of available antibiotics and developing new sources of antibiotics and complimentary measures such as point-of-care diagnostic tools, vaccines and better animal husbandry. Experts estimate it could take up to 10 years to bring new antibiotics to the market. (Note: No new class of antibiotics have been produced since 1987: existing antibiotics have been recalibrated and/or used in various combinations.)

Data: Tracking AMR and antibiotic use in food production is inadequate or unavailable so 'Risk' or Scientific Assessment' cannot be defined easily:

Even at this juncture, there is still so much to learn about the spread of AMR. New AMR is being discovered as more research is conducted so the AMR landscape is fast changing making it difficult for policy makers to set priorities and agree on strategic interventions. On global use of antibiotics, the available data on human use is not comprehensive. But data on antibiotic use in animals, agriculture and aquaculture is of particular concern as substantial meaningful data is not available. Only a few countries have implemented rigorous collection of data⁶ and there is a considerable lag in the information coming out of the various industry groups. These gaps must be

⁴ Between the same kinds of bacterial, i.e. E.coli that cause urinary tract infections and E.coli that cause food poisoning, or between different kinds of bacteria - Ecoli and antibiotic-resistant Staphylococcus aureus (MRSA). (See Footnote 3.)

⁵ Dept. of Agriculture records "In animals, AMR infections result in reduced animal health, welfare, biosecurity and production outcomes. AMR infections in animals can result in the transfer of resistant bacteria to people who come into contact with them. **AMR infections in animals destined for human consumption also pose a risk via foodborne transmission.**" See <http://www.agriculture.gov.au/animal/health/amr?wasRedirectedByModule=true>

⁶ <http://mbio.asm.org/content/7/2/e02227-15.full>

In this article, the current knowledge and knowledge gaps in the emergence and spread of antimicrobial resistance (AMR) in livestock and plants and importance in terms of animal and human health are discussed. Some recommendations are provided for generation of the data required in order to develop risk assessments for AMR within agriculture and for risks through the food chain to animals and humans.

addressed - evidence based policy-making cannot take place if the data and full disclosure of use is not available. Policies based on precautionary measures may provide better public health options.⁷

The Global Food Chain' Dependency upon Antibiotics: Imports and Domestic Production:

As antimicrobial resistance (AMR) develops from the use of antibiotics - particularly the overuse, misuse or inappropriate use of these precious drugs - **all traded products associated directly or indirectly with the use of antibiotics could transmit AMR.** This includes through the animal and human global food chain and also trade associated with tourism and medical or cosmetic tourism can also transmit AMR.

Reputational Issues Around Food Trade: While AMR is still to be comprehensively understood by consumers there can be little doubt, as AMR evidence continues to emerge, brands and reputations may be trashed if there is the perception of food exports being implicated as transmitting AMR. It is in the national interest for Australia to do everything possible to minimise AMR development, ensure we have the highest standards of testing and tracing - not only of Australian food but also inputs into Australian products entering through the global food chain, as well as food selling directly into the Australian market.

International Investors Reacting: The optics around AMR as well as the policy substance is important, particularly when media becomes more focused on how AMR is being address. The AMR issue is now in the sights of some 54 influential asset managers with over \$1 Trillion in assets. They have already warned some major global food corporations of the need to substantially address AMR, particularly to stop non-therapeutic use of antibiotics being administered to animals in the food chain.⁸

UN Special Session on AMR: The UN political dialogue was useful as it helped expose the scope of AMR as this quote from the DG of the FAO records *"AMR is a problem not just in our hospitals, but on our farms and in our food, too. Agriculture must shoulder its share of responsibility, both by using antimicrobials more responsibly and by cutting down on the need to use them, through good farm hygiene"*. But the UN failed to set targets to limit antibiotic use. This outcome may reflect the highly sensitive political status of AMR. Developing countries' lack of access to critical antibiotics in many health settings aligned with other situations where antibiotics have to be used to counter the lack of clean water or sewage systems. This contrasts starkly with developed countries access and levels of use, particularly in food producing countries. Developing and middle-income countries are likely to be sensitive to attempts to address AMR in food, which could stymie their food export industries.

Non-Government and Health Expert's Response Following the UN AMR Discussion:

Reflecting some disappointment at the failure at the UN to set measurable targets to reduce AMR use globally, a new coalition of experts and reputable health institutions is now operating to maintain political pressure to deal with AMR. This coalition, Conscience of Antimicrobial Resistance Action (CARA), intends to "...work to hold the United Nations and other international bodies, national governments, the private

⁷ http://www.foodsafety.govt.nz/elibrary/industry/Precautionary_Approach-Background_Paper.htm#P32_5837

This link is from the NZ Government website on the use of the precautionary principle is relevant given it will be Food Standards Australia and New Zealand that will be responsible for developing national treatment testing measures.

⁸ <http://www.fair.org/news-item/1-trillion-investor-coalition-demands-corporate-action-on-systemic-overuse-of-antibiotics-press-release/>

sector, and civil society to the commitments they have made to ensure sustainable access to effective antimicrobials.”⁹

Summary: These developments signal that the issue of AMR is gaining political and media traction. But also as important is the scientific research now being undertaken, and with the new genomics and metagenomics toolkit, revelations on the global scope of the AMR is likely to place substantive pressure on the current model underpinning global food production and trade. Trade Agreements, already highly politically controversial, may be seen as part of that AMR problem. The details below represent some of the issues requiring attention – the issues raised are not exhaustive.

International Trade Context - AMR and 'One Health' Policy Cohesion:

The WTO rules and obligations underpin FTAs but they contain higher levels of obligations, consultations and regulatory procedures embedded in them. Both WTO and FTA trade frameworks contain obligations that can impact or be affected by AMR. **Policy makers and trade negotiators should be sensitised to these issues. From a 'One Health' policy cohesion perspective pro-active action is needed to take account of AMR strategies or to exempt AMR measures from some of these trade rules:**

- Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Chapters address food safety issues, standard setting and labelling¹⁰ with rules and obligations that need to be sensitised to addressing AMR.
- Also relevant is the application and legitimacy accorded to the international food standards developed by the Codex Alimentarius Commission. Codex's earlier work ten years ago on AMR has to be updated. Australia is to work with the UK Chair and the US to develop the agenda and input to an Intergovernmental Meeting on AMR to be held in Korea in 2017 – outcomes not expected for a couple of years.
- And important to note, unlike the WTO, FTA's contain the added contentious element of Investor State Dispute Agreements (ISDS) and so-called 'welfare exceptions are not necessarily a guarantee against ISDS activity.
 - Concept of 'least restrictive measures', or understandings of what constitutes 'discrimination' can be very broadly interpreted in initiating or threatening to initiate ISDS cases.
 - Policy making options can be skewed to avoid confrontation with a company or its supportive government's lobbying. Influences on 'policy' are difficult to identify because there is no capacity to access relevant policy input or formal deliberations.

Can we test for AMR at the border and remain consistent with WTO/FTA?

Yes: WTO monitoring rules and procedures applied at a global level such as '**National Treatment**' provisions are designed to create a non-discriminatory and transparent trading environment applied equally to domestic and imported products and would enable AMR testing. Another option is to develop individual **Mutual Recognition Agreements (MRA)** but this approach does not deliver comprehensive surveillance for AMR at the border.

⁹ http://www.bsac.org.uk/wp-content/uploads/2016/09/alliance-announcement-9.17_FINAL.pdf

¹⁰ https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm

Of these two options, testing for AMR on the basis of **WTO National Treatment Rules** is the most comprehensive and efficient:

- Would establish *systematic* testing for AMR as it would covers products entering the food chain from domestic production and from the global food chain in advance of consumption.
- Enables the collection of key AMR data for Australia's reporting to the World Health Organization's AMR Global Surveillance System ([GLASS](#))¹¹
- Establishing such trade standards provides both incentives and inducement to address AMR.
- Would not preclude also developing complementary Mutual Recognition Agreement, which can be used to influence /develop specific markets and provide training. Some of the differences outlined in Attachment 1:

Food safety measures and Consumer Information

The WTO's SPS and TBT provisions while allowing for national interest measures, and include emergency situations, they assume concepts of '*scientific certainty*' and policy flexibility linked to '*least restrictive methods*' that may not be appropriate to the AMR global health security issue – particularly given the lack of verifiable data and extent of AMR transmission. Also the WTO dispute provisions integral to these two Chapters implicitly and explicitly impose particular rules and restrict some policy options.

Free Trade Agreements (FTAs) include most of the WTO provision for SPS and TBT but also introduce higher levels of obligations, particularly associated with 'trade facilitation' and 'harmonisation' objectives and include mandatory dispute and consultative processes. And most problematically, these new FTAs include Investor State Dispute Provisions (ISDS).

AMR Health Security Policy - Some possible areas of conflict:

- To minimise AMR will require active transformation of the global food-producing model and a recalibration in the use of antibiotics away from growth promoters/non-therapeutic use. Claims for therapeutic use will likely require active monitoring, regulation or use or sanctions if trade reputation is being damaged. Health experts are critical of the very high level of so-called 'therapeutic use' generally only based on self-assessment. For example, this recent criticism of using voluntary standards to stop antibiotic use for growth promotion which according "... to figures from the [US] industry trade group the Animal Health Institute, growth promotion accounts for only 10% to 15% of total antibiotic use in livestock and poultry".¹² The difficulties of justifying therapeutic use are significant. This problem is likely to be replicated in many countries once data becomes available.

¹¹ <http://www.who.int/antimicrobial-resistance/publications/surveillance-system-manual/en/>

¹² The report containing the Petition to the FDA can be accessed from this website:
<http://www.cidrap.umn.edu/news-perspective/2016/09/petition-calls-fda-limit-antibiotic-use-food-animals>

- Another major problem is the use of antibiotics relevant and often critical for humans which are used for animals.¹³ This is one of the key problems that must be addressed. The WHO's guidance on this matter is being ignored by many key food producing countries. The EU and several other countries enable the use of a last line antibiotic – colistin- to be used in food production.¹⁴ The US does not use colistin in animals but health experts are lobbying to stop the use "...for seven classes of antibiotics recognized as important to human medicine: macrolides, lincosamides, penicillins, streptogramins, tetracyclines, aminoglycosides, and sulfonamides. ¹⁵ Australia's key experts also have concerns around these issues that should be understood by the Committee, one being to ensure carbapenems are not used in food.
- AMR strategies may therefore have to be backed up by regulatory and/or mandatory policies. The different regulatory or deregulatory frameworks among TPP partner countries will not be simple to negotiate unless clear national interest priority is accorded to this health security issue.
- Significant policy changes may be resisted strongly by global food producers. To note: in TPP and other FTA consultation processes representatives of global producers can participate in policy consultation processes – in contrast, in the WTO only government representatives participate in such formal negotiations.
- Also with increasing understanding of the transmission of AMR consumers demand for substantive information on labels will increase – these policies are generally resisted by the food industry. The current labelling arrangements in Australia are unlikely to provide the extent of information sought by consumers concerned about AMR.

¹³ <https://www.washingtonpost.com/news/to-your-health/wp/2016/09/09/newest-superbug-found-in-a-connecticut-toddler/>

¹⁴ <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=21403>

¹⁵ See footnote 12 for an overview of this Report to the US FDA.

Overview of WTO Consistent Testing of Food:

To note: No systematic testing program is currently in place to test for AMR.

Some separate random testing takes place in various settings, federal, state and academic/industry but this range of testing is not systematically collated or necessarily available to the public or health officials. The following chart illustrates some of the benefits of both option but National Treatment has more capacity to systematically monitor the food chain for AMR.

<p>National Treatment Provisions: Are WTO (and FTA) consistent and facilitate capacity for testing procedures or other measures deemed necessary to counter the development or transmission of AMR.</p> <p>Enables 'systematic' testing <u>and</u> collection of AMR data of domestic production and at the border imports;</p> <p>Levels of testing and/or AMR targets can be adapted for greater or lesser surveillance as necessary.</p> <p>National Treatment provisions signal to other countries the type of approaches acceptable to consumers. (EU food safety regulations have been successful in improving global food production techniques.)</p>	<p>Mutual Recognition Agreement (MRA) Are WTO and FTA constant and tend to be the preferred option in FTAs like the TPP.</p> <p>MRA's can be useful in developing best practice in both Parties' markets and also enable options for more specific inspections.</p> <p>These bilateral/plurilateral arrangements are 'negotiated outcomes' May involve trade-offs.</p> <p>MRA's are partial and exclusive to the Parties therefore less effective in capturing AMR across the food chain or in setting the benchmark for collection of data to assist addressing AMR globally.</p>
<p>The policy development process National Treatment provisions are <u>negotiated at the domestic level</u> and reported to the WTO. This enables greater capacity for national policy decision-making.</p> <p>Are applied globally</p> <p>MRAs are not inconsistent with National Treatment but there may be elements in MRAs that would not be as compatible with the global application of National Treatment provisions.</p>	<p>The policy development process Mutual Recognition Agreements are developed through bilateral negotiations so can have the capacity to focus on specific concerns, depending upon the partners to the Agreement.</p> <p>Is not global in its effect.</p> <p>May be less effective in promoting Australia's public health AMR agenda if large domestic food exports are at stake. Or conversely, negotiating with a significant import market.</p>