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The pros and cons of animal health harmonisation

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Summary

It has been argued that the global harmonisation of animal health procedures, regulations and responses will improve animal health and provide economic benefits. Harmonisation of regulations can be driven by trade reform, such as multilateral or bilateral agreements, or as a response to private quality assurance programmes.

At an international level, trade reform is currently focused on reducing the costs of trading between countries. To achieve this, bilateral agreements, where possible, are harmonising regulations throughout all sectors of the economy. However, as with any new developments, there are both positive and negative outcomes that should be explored to understand the net effect of these changes on animal health, the economy and society.

In this article, the authors debate the economic foundations of harmonisation, explore alternative methods to achieve it, and discuss its pros and cons to more fully understand the opportunity costs from countries adopting the same level of risk to animal health.

Keywords

Animal health – Harmonisation – Regulation – Trade – Unintended consequences.

Introduction

With major gains from tariff reform being realised, trade reform policy has shifted its focus towards the removal of non-tariff barriers and the harmonisation of regulations to increase the economic gains from trade integration. As the differences in regulatory frameworks between countries decrease, the costs of doing business between those countries also decrease, and a wider range of goods can enter the market at lower prices, thus benefiting consumers. This is the law of comparative advantage that underpins free trade (1).

Harmonisation of regulations can provide real economic and social gains, especially in countries where regulations and institutions are lax (2). Therefore, the drive for harmonisation has become central to the World Trade Organization (WTO) and the quest for economic growth. Additionally, the adoption of private regulations can enable some individuals to take advantage of niche markets and higher prices by meeting social preferences (3).

However, the gains from harmonisation have been challenged by two central arguments. The first states that analyses typically only search for a positive impact on one sector of an economy from harmonisation (4), and fail to consider the complex spillover effects (both positive and negative) that this change may have across all sectors of society and the economy (5, 6, 7).

The second explains that trade is about 'games of power' and that a country's hegemony can influence the level of harmonisation to benefit its own economy and not that of its

trade partners (8). Thus, a failure to understand the complex changes from harmonisation, i.e. information asymmetry, may lead to regulatory capture (9) and to a country adopting a level of risk (e.g. attitudes to antibiotic use, food health standards) that was unpalatable to its residents before harmonisation (10, 11). As Hassoun (12) reflects, the design and implementation of harmonisation may actually reinforce conditions of poverty and inequality within a country. Not every country has enjoyed harmonisation, and the cost of re-establishing a country's independence to set its own regulations comes at a cost. By the end of 2020, it is predicted that the United Kingdom's (UK's) economy will have lost £ 200 billion in four years during 'Brexit', the departure of the UK from the European Union (EU) (13).

Animal health harmonisation creates both positive and negative effects on a country, but its true impact may only be fully realised once harmonisation has been either implemented or removed. Therefore, careful debate before either the implementation or the dissolution of harmonised regulations is required, to consider the wider impacts on society. The discussion is complex, as animal health harmonisation applies equally to:

- production inputs, e.g. the registration of pharmaceuticals, feedstuffs
- regulated husbandry practices, e.g. cage size, animal welfare practices, and slaughter protocols

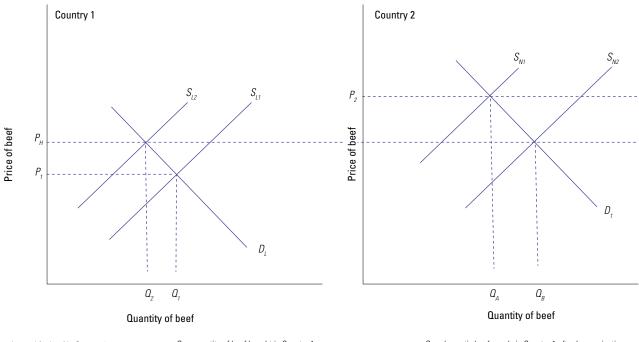
- output definitions, e.g. what age is veal?
- protocols for international animal health emergencies, e.g. defined rules to apportion costs and responsibilities when dealing with animal diseases, their prevention, detection, and treatment (14).

To explore this multifaceted problem, this article first outlines the basic economic foundations associated with harmonisation, then debates how harmonisation can occur via alternative government agreements and private interventions. The pros and cons from harmonisation are then examined and final comments provided.

Harmonisation and trade

The economics of harmonisation and trade focus on the impacts on producers and consumers. Let us consider the case of two countries (Country 1 and Country 2) seeking to harmonise regulations on beef health requirements (Fig. 1).

Country 1 has lower animal health standards and production costs. In this country, producers can sell a kilogram (kg) of beef at a certain price P_1 . At this price, consumers will buy Q_1 kgs of beef. Country 2 has more stringent animal health regulations, and producers must charge P_2 to remain viable, but at this price consumers in Country 2 will only buy Q_A kilograms of beef.



- D_1 : demand for beef in Country 2
- D_L : demand for beef in Country 1
- P_1 : price of beef in Country 1
- P₂: price of beef in Country 2
- P_H : price of beef after harmonisation
- Q_1 : quantity of beef bought in Country 1
- Q_2 : quantity of beef bought in Country 1 after harmonisation
- Q_A : quantity of beef bought in Country 2
- $Q_{\!\scriptscriptstyle B}$: quantity of beef bought in Country 2 after harmonisation
- $\mathcal{S}_{\!\scriptscriptstyle L1}\!:$ domestic beef supply in Country 1

- $\mathcal{S}_{\!\scriptscriptstyle L\!\scriptscriptstyle Z}\!:\,$ domestic beef supply in Country 1 after harmonisation
- S_{N1} : domestic beef supply in Country 2
- $\mathcal{S}_{\mathit{N2}}$: domestic beef supply in Country 2 after harmonisation

Fig. 1 How trade harmonisation changes market prices, production and demand

If the costs of harmonisation allow beef to be sold at P_H /kg, then regulations have increased Country 1's costs and decreased Country 2's costs. Now the quantity of beef consumed in Country 1 falls to Q_2 while in Country 2, the quantity of beef being bought increases to Q_B . In this example, there are winners and losers in harmonisation, and economics can provide an understanding of the likelihood of these impacts across society.

What the basic story of harmonisation neglects is: who sets the standards and second-round effects of change? For example, if standards were set to Country 2 levels, Country 1 may not be able to produce any beef. Alternatively, if Country 1's standards were adopted, they may introduce a level of risk that results in adverse animal and human health impacts from outbreaks of exotic disease (10). Additionally, second-round effects of change can negatively affect profits, leading to structural change in the production sector and labour redistribution (15, 16, 17).

Both theoretically and practically, these are vital issues in the harmonisation of animal health regulations. The next section explores the private or public mechanisms that set in motion the process of harmonisation.

Harmonisation standards: public versus private?

Harmonisation can be implemented in three ways. The first is via multilateral agreements through the WTO; the second is via bilateral agreements (between two countries) or plurilateral agreements (among three or more countries); and the third is through the introduction of private standards.

Multilateral trade agreements: the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

With 164 Member Countries and 24 observer nations (www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e. htm#observer), the WTO provides a unified platform for negotiations to develop rules for trade in goods, services and intellectual property, and to deal with disputes. Central to the discussion here is the argument that an individual country's control is diminished in a larger group and as these processes unfold (18).

The WTO recognises several relevant international standard-setting bodies as responsible for developing the global standards for trade harmonisation in the areas of animal and plant health and food safety. This is enshrined in the WTO Agreement on the Application of Sanitary

and Phytosanitary Measures (SPS Agreement), which was adopted in 1995 (19). This Agreement sets out the rights and obligations (and exceptions) for WTO Members with respect to measures that address animal and plant health risks, and food safety risks. Specifically, the SPS Agreement relies on three international standard-setting bodies (also known as the 'Three Sisters' of this Agreement) for developing SPS-related standards, guidelines and recommendations:

- the World Organisation for Animal Health (OIE), which specifies animal-health-related standards
- the Secretariat of the International Plant Protection Convention (IPPC), which specifies plant health standards
- the Codex Alimentarius Commission, which specifies food-safety-related standards, including acceptable levels of chemical use in food production systems (e.g. maximum residue limits).

In this respect, the SPS Agreement views harmonisation as the procedure by which countries base their SPS regulations on the international standards, guidelines or recommendations developed by the Three Sisters, and the Agreement encourages countries in this process.

Although the Three Sisters set the standards, each country can still set its own appropriate level of protection (ALOP) and standards if it bases these adjustments on science. The ALOP is the level of risk to a country's economy, ecosystem and human population that a country is willing to accept from being involved in trade.

Bilateral and plurilateral trade agreements

Reaching consensus in multilateral agreements is a laborious process and countries engage in bilateral/plurilateral agreements, often called 'Free Trade Agreements' (FTAs), to avoid protracted negotiations.

However, harmonising animal health and food safety regulations through this bilateral/plurilateral process can result in a set of mutually agreed regulations that differ from those recognised under the SPS Agreement.

In this situation, the ALOP among countries is harmonised and, in certain situations, the regulatory authority can move away from public institutions towards corporate power. Labonté *et al.* (7) detail the impact of the Agreement between the United States of America (USA), the United Mexican States and Canada (USMCA) on Mexico and Canada and the transfer of power to USA corporations in the public health sector. Moreover, the desire to harmonise with the US ALOP resulted in the removal of Canada's right to use dispute settlement to resolve investor state disputes.

Redirection towards corporate control may create outcomes where those who set the risk are not responsible for dealing with the negative outcomes from that risk. It is within bilateral/plurilateral settings that 'games of power' become evident and are pivotal in strategically manipulating the outcome of the deal (8). Consequently, rarely do FTAs lead to free trade. Rather, FTAs stipulate a set of conditions that solidify advantage to one or more countries at the expense of another.

Private standards

Private standards or quality assurance programmes can be 'top down' (e.g. from an oligopolistic purchaser) (20), determined by consumer 'bottom up' (e.g. preferences) (3, 21). Such standard-setting programmes mechanism operate а signalling between producers, retailers and consumers (22). social expectations may drive private standards and provide incentives for producers to meet the desires of the public, they are not regulations (23). Nevertheless, failure to comply with these private standards may still result in some form of penalty, such as receiving a lower price or being denied market access. Private standards are considered a 'mixed blessing', as they can both enhance the SPS Agreement and, in some situations, be considered a barrier to trade (24, 25).

In countries with weak institutions, the adoption of basic private standards may provide significant gains in terms of economic activity and animal welfare (26), but in countries with strong institutions, the gains are likely to be lesser. In some situations, private standards can be a response to creative marketing, when a lack of information or misinformation is used to gain a greater share of a market through fear. The 2016 hormone-free beef promotion from fast-food chain Hungry Jack's is one such example (27).

Why harmonise?

Central to the debate about harmonisation is the question: 'why would a country be willing to give up the sovereign right to set its own regulations?' Whose regulations should countries adopt and are these standards higher or lower than those set by the international standard-setting bodies recognised by the WTO SPS Agreement? Moreover, do all signatories of a trade deal benefit equally? The way in which harmonisation is put into practice has a considerable influence on the benefits that may or may not accrue. To harmonise or not to harmonise is thus a problematic choice. In the following section, the authors outline the common pros and cons of harmonisation in both the public and private sector.

Possible positive effects of animal health harmonisation

The five points below summarise the harmonisation debate, when harmonisation is defined only as the removal of barriers. In some cases, harmonisation can lead to more regulation but that possibility is not examined here.

a) The harmonisation of regulations and the cutting of red tape will improve efficiency (28) and reduce costs (29). This argument relies on the comparative advantages in reducing compliance, labour and paper work costs once harmonisation has occurred, as well as 'unpleasant surprises' that may cause delays in access to markets or consignments being refused. However, harmonisation may also lead to decreased competition in the long run. For example, if domestic conditions before harmonisation allowed the development of monopolies and oligopolies, then those companies may go out of business once regulations are harmonised. If that occurs, there is a possibility that the surviving company/companies may revert to monopolistic or oligopolistic behaviour in the long term (30).

b) Government regulatory institutions and legal frameworks are unable to keep pace with improvements in technology. If a multilateral regulation and verification process were adopted (i.e. if an object passed the regulations standards in one country, it would automatically pass the regulations in another country), the rate at which new goods enter the market would increase, and all cost savings could be diverted into further research or price reductions.

This argument 'sells' the idea that the next miracle cure is on the horizon (31), or that regulations are preventing a new practice which could unshackle current production constraints (32).

c) The cost of developing good institutions can be prohibitive for some countries and their limited public funds would be better allocated to some other activity. In other words, if a country with good institutions deems the practice safe, then a country with under-resourced institutions can benefit from adopting the findings of other countries. In this case, the opportunity cost of having sound science should not be put in the way of helping resource-strapped countries gain from the introduction of good veterinary practices and drugs (33).

In such circumstances, harmonisation can be of particular benefit if there are few animal health products currently being used. By understanding the concepts of diminishing marginal benefits, there are significant gains from the introduction of basic animal health inputs to production.

d) Greater market certainty, freedom and profits will encourage a new wave of funding, leading to potential new cures in areas where little research is currently being undertaken (34).

e) Clearly defined and harmonious procedures and costsharing mechanisms for dealing with emergency veterinary responses will reduce the costs of dealing with emergency outbreaks. A potential pooling of resources may take place, reducing the costs of monitoring and enforcement.

By harmonising procedures, not only should the time required to deal with an emergency issue be reduced, but disruption in trade should also be minimised, as attitudes to risk are homogeneous, and disputes avoided.

The arguments for harmonisation via private standards may be theoretically compelling at a basic level, as they demand the removal of unnecessary government interference in the market, and assert that, by creating a level playing field, the best provider will emerge victorious in a competitive market. In such a classical foundation, two key assumptions must hold: markets must be perfect and private institutions must be fundamentally more efficient than government agencies.

These assumptions are based more on faith than on fact. Health, food safety and animal welfare are a combination of both private and public goods, and those markets are prone to market failure and under-investment (35). Consequently, rules and regulations are designed not only to address those market failures (36), but to reflect society's expectations, minimise the risk of adverse events, and, in part, ensure there is some balance between those who create the risks and those who are severely affected by adverse events (9).

Gray (11) suggests that applying static neo-classical economic models to the question of regulatory integration supports harmonisation, in that it facilitates the free movement of direct investment, technology and labour, but ignores the cost of diminishing a nation's right to self-governance and wider social settings. This includes animal health. It is therefore prudent to also examine the potential negative impacts of harmonisation.

Possible negative effects of harmonisation

A series of studies have challenged the argument that greater deregulation is always beneficial.

a) The harmonisation of ALOP implies that all countries share the same opportunity costs (35) and have the same values and attitudes to the precautionary principle. (This

is patently not the case. For example, Europe and the USA have opposing views on the use of growth-promoting hormones in animal production.) The precautionary principle suggests that, in cases where there is a risk but insufficient information, waiting to collect new information provides net social gains (37). Regulations are designed to collect data, prevent the concentration of market power, avoid unintended consequences and reflect society's values (9). Before harmonisation is sought, decision-makers need to truly understand the changes caused to all sectors of the economy before they can determine its benefits.

- b) In the case of public health, the reduction in regulations has not led to an expansion of private research funding or necessarily to a reduction in costs. Rather, Baker et. al. (5) found that harmonisation of intellectual property rights reduced economic welfare, due to the decreasing number of pharmaceutical firms, which enabled them to increase their prices. With the global animal health pharmaceutical market dominated by ten key firms, and high 'up-front' fixed costs as the barrier to entry (38), harmonisation may lead to fewer firms, resulting in higher animal health costs.
- c) Whiting (39) suggested that a consistent ALOP can lead to the freedom of animal movement between countries, which could introduce exotic diseases into naïve populations. This issue was raised with regard to the trade deal between the USA and Canada, with the threat of anaplasmosis spilling over into the Canadian herd.
- d) Adamson (10) highlighted the danger of hegemonic relationships in harmonisation by taking the example of a small country which is also a net exporter. He used Australia as the net exporting 'small country' (with a domestic market of 24.5 million people), and noted that 80–90% of Australia's agricultural income is derived from export earnings. Thus, if market access is denied, the domestic population cannot consume the excess production, leading to price reductions. In this case, not only is the industry that is denied market access in trouble, but all industry substitutes are also affected as they suddenly face competition at a much lower price. In extreme situations, this could lead to a sudden reduction in national herd size, and a long-term loss of export markets to competitors.

Conclusions

While there can be great gains from harmonisation, the choice to harmonise is a sovereign right. The benefits and risks of harmonisation are not constant across countries, nor are all regulations a burden on society. It is up to individual countries to determine if their regulations should be harmonised. Further, the level of risk that a country is willing to accept from harmonisation needs to be debated in a public forum.

The desire to harmonise may originate with net exporters, net importers, or those countries aiming to gain market access for goods. Considering the specifics of the production sector involved, the risk of adverse or unintended consequences and the potential redistributive effects is essential, as not all countries and not all economies are the same. Care must be taken to consider who is setting the standards, and which countries bear the cost of adopting harmonised standards.

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Les avantages et les inconvénients de l'harmonisation dans le domaine de la santé animale

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Résumé

Il a souvent été avancé qu'en matière de santé animale, l'harmonisation des procédures, des réglementations et des interventions à l'échelle mondiale améliore la situation zoosanitaire globale tout en apportant des bénéfices économiques aux pays. Une telle harmonisation réglementaire peut être le fruit d'une réforme du commerce, notamment par le biais d'accords multilatéraux ou bilatéraux, ou bien constituer une réponse aux programmes d'assurance qualité privés.

Au niveau international, la réforme du commerce est actuellement centrée sur la réduction des coûts qu'il entraîne pour les pays. Dans cette perspective, des accords bilatéraux sont conclus chaque fois que possible afin d'harmoniser les réglementations dans tous les secteurs de l'économie. Néanmoins, comme dans toute évolution nouvelle, il en résulte des retombées aussi bien positives que négatives qu'il convient d'analyser afin de bien comprendre l'incidence nette de ces changements sur la santé animale, l'économie et la société.

Après avoir débattu des fondements économiques de l'harmonisation, les auteurs examinent les méthodes alternatives qui permettent d'obtenir le même résultat; ils font aussi le point sur les avantages et les inconvénients de l'harmonisation afin de mieux comprendre le coût d'opportunité qu'elle induit pour les pays adoptant le même niveau de risque en santé animale.

Mots-clés

Échanges internationaux – Effets indésirables – Harmonisation – Réglementation – Santé animale.

Ventajas e inconvenientes de la armonización en el ámbito de la sanidad animal

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Resumen

Se ha postulado que la armonización mundial de los procedimientos, reglamentos y respuestas en materia de sanidad animal redundará en un mejor estado sanitario de los animales y reportará beneficios económicos. El impulso para proceder a una armonización reglamentaria puede tener su origen en una reforma del comercio, a raíz por ejemplo de acuerdos multilaterales o bilaterales, o responder a programas privados de garantía de la calidad.

A escala internacional, la reforma de los mecanismos comerciales apunta ahora básicamente a reducir los costos del comercio entre países. Para lograrlo se suscriben acuerdos bilaterales que, cuando es posible, entrañan una armonización reglamentaria en todos los sectores de la economía. Sin embargo, como ocurre con todas las novedades, ello tiene repercusiones positivas y negativas, que conviene analizar para aprehender el efecto neto de estos cambios en la sanidad animal, la economía y la sociedad.

Los autores examinan los fundamentos económicos de la armonización, plantean métodos alternativos para llevarla adelante y dan cuenta de sus ventajas e inconvenientes para conocer mejor los costos de oportunidad que trae consigo la adopción de un mismo nivel de riesgo zoosanitario por parte de los países.

Palabras clave

Armonización — Comercio — Consecuencias imprevistas — Reglamentación — Sanidad animal.

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