Transboundary and Emerging Diseases

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ORIGINAL ARTICLE

International Trade Standards for Commodities and Products Derived from Animals: The Need for a System that Integrates Food Safety and Animal Disease Risk Management

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Summary

A case is made for greater emphasis to be placed on value chain management as an alternative to geographically based disease risk mitigation for trade in commodities and products derived from animals. The geographic approach is dependent upon achievement of freedom in countries or zones from infectious agents that cause so-called transboundary animal diseases, while value chain-based risk management depends upon mitigation of animal disease hazards potentially associated with specific commodities or products irrespective of the locality of production. This commodity-specific approach is founded on the same principles upon which international food safety standards are based, *viz.* hazard analysis critical control points (HACCP). Broader acceptance of a value chain approach enables animal disease risk management to be combined with food safety management by the integration of commodity-based trade and HACCP methodologies and thereby facilitates 'farm to fork' quality assurance. The latter is increasingly recognized as indispensable to food safety assurance and is therefore a pre-condition to safe trade. The biological principles upon which HACCP and commodity-based trade are based are essentially identical, potentially simplifying sanitary control in contrast to current separate international sanitary standards for food safety and animal disease risks that are difficult to reconcile. A value chain approach would not only enable more effective integration of food safety and animal disease risk management of foodstuffs derived from animals but would also ameliorate adverse environmental and associated socio-economic consequences of current sanitary standards based on the geographic distribution of animal infections. This is especially the case where vast veterinary cordon fencing systems are relied upon to separate livestock and wildlife as is the case in much of southern Africa. A value chain approach would thus be particularly beneficial to under-developed regions of the world such as southern Africa specifically and sub-Saharan Africa more generally where it would reduce incompatibility between attempts to expand and commercialize livestock production and the need to conserve the subcontinent's unparalleled wildlife and wilderness resources.

Introduction

Current international trade standards based on the geographic distribution of transboundary animal diseases (TADs) exclude large numbers of livestock producers in southern Africa from high-value markets for livestock products. This has prompted proposals for alternative, non-geographically based international standards founded on commodity-specific risk management (Thomson et al., 2004, 2009; Scoones et al., 2010). Limited progress in adoption of this alternative approach has resulted; the World Organization for Animal Health (OIE), for example, has accepted the concept of commodity-based trade (CBT) (OIE, 2012b) but mechanisms for practical implementation remain limited. The reasons for this are probably as follows: (i) the historical focus on geographic approaches that has characterized management of animal health trade risks for many decades, (ii) poor acceptance by both importing and exporting countries of non-geographic standards, (iii) inadequate acceptance of the principle of equivalence and (iv) preoccupation in many parts of the world with managing crises occasioned by TADs such as foot-and-mouth disease (FMD), avian influenza, African swine fever and Rift Valley fever (Costard et al., 2009; Grobbelaar et al., 2011; University of Pretoria/Agricultural Research Council, 2011; EMPRES/FAO-GLEWS, 2012).

More TADs are endemic to southern and East Africa than any other part of the world, resulting from a unique wildlife heritage (Bengis et al., 2004). At the same time, southern Africa in particular has begun to invest in transfrontier conservation areas (TFCAs), based in large part on a growing recognition by African governments that they have a global comparative advantage when it comes to wildlife-based tourism, increasingly key to regional economic growth (Osofsky et al., 2008; Thomson et al., 2013). The mixed land use approach that characterizes TFCAs is poised to increase the extent and intensity of livestock–wildlife interaction in large parts of southern as well as East Africa, a consequence being that the historical conflict between livestock interests based on expansion of livestock production and access to markets on the one hand and wildlife conservation on the other, is also intensifying (Osofsky et al., 2005; Thomson et al., 2013). The TFCA concept promotes free movement of wildlife over large geographic areas, whereas the present approach to the control of TADs (especially in respect of directly transmitted infections) is to prevent movement of susceptible animals between areas where TADs occur and areas where they do not, largely through extensive veterinary cordon fencing, and to similarly restrict trade in commodities[1] derived from animals in 'infected areas'. The result is incompatibility between (i) current regulatory approaches for the control of diseases of agro-economic importance and (ii) the vision of vast conservation landscapes without major fences or other artificial movement barriers. Livestock agriculture and the wildlife conservation sector are both vital for balanced rural development in southern and East Africa and a way to finally resolve more than a half century of inter-sectoral land use conflict would seem to lie within the realm of animal health policy (Osofsky, 2010; Thomson et al., 2013).

A subject of current debate is how biological risk management systems for (i) food safety and (ii) control of animal pathogens that can be spread through traded commodities and products can be integrated to render the current disparate systems simpler, more effective, less costly and easier to audit and certify. Some progress has been made in development of a common approach to standard setting between the OIE and the Codex Alimentarius Commission (CAC) related to anti-microbial resistance standards, identification/traceability and animal feeding (OIE, 2011). More recently and promisingly, the OIE and Codex Alimentarius have been focusing on working together to take a 'whole food chain' approach to food safety (OIE, 2012d; Oidtmann et al., 2013). This is an important development because, as explained below, the OIE and CAC standards are based on different principles/approaches. Furthermore, because food manufacturing is increasingly complex and typically involves a number of enterprises along convoluted production/value chains, it is logical that risk management needs to be applied along those value chains. The practicality of such an approach for managing animal disease threats has been advocated by recent provision of a guideline by the Food and Agriculture Organization (FAO, 2011).

The thesis of the argument presented here is that introduction of integrated sanitary risk management along value chains is logical and necessary for global economic development involving trade in animal commodities and products. We contend that such an approach is technically relatively straightforward through integration of the HACCP approach with the concept of CBT. Apart from providing a simpler and more auditable alternative to geographically based sanitary control, the integrated approach would obviate some of the unintended but unfortunate socio-economic and environmental consequences of the current system.

Current Sanitary Management of International Trade in Commodities and Products of Animal Origin

The primary purpose of the system of agreements among member countries that directs the activities of the World Trade Organization (WTO) is to encourage global trade to flow as freely as possible while at the same time minimizing the potentially undesirable effects of free trade, thereby promoting global development and well-being (WTO, 2009). In the case of trade in animal commodities and products, the two most potentially detrimental effects relate to safety of foodstuffs for human consumption and the potential for those foodstuffs to spread animal disease-causing agents capable of resulting in serious damage to the health of people and/or animals in importing countries, with consequent negative impacts on rural and national economies. International standards and guidelines for addressing these hazards are provided by the Agreement on the Application of Sanitary and Phytosanitary Measures [SPS Agreement] (WTO, 2012).

Article 3 of the SPS Agreement stipulates that sanitary provisions adopted by member countries should be based on international standards, guidelines and recommendations where they exist, while Article 5 implies that risk analysis, conducted in accordance with international guidelines, is the foundation for effective management of SPS hazards. Flexibility in application of methods to ameliorate these risks is provided by Article 4 dealing with 'equivalence'. This means that as long as the exporting country can objectively demonstrate that its system provides the same level of risk mitigation as the published international standard, it should be accepted by importing WTO member countries. These provisions as they relate to terrestrial animal diseases are covered by Chapter 5.3 of the OIE's Terrestrial Animal Health Code (TAHC) (OIE, 2012a).

The relationship between international standard-setting bodies (ISSBs), the standards themselves and guidelines for managing food safety and spread of animal diseases through trade has been presented and discussed by Thomson et al. (2013). That paper points out that although the infectious disease risks associated with food safety are generically similar to those for animal disease dissemination by commodities and products intended for human food, the methodologies recommended by the two ISSBs concerned – the CA Commission and the OIE – differ. The CA, as is universally the case for systems designed for management of food safety, adopts HACCP (FAO, 2006), while the OIE's TAHC traditionally adopts the concept that risk associated with trade in animal commodities is preferentially mitigated by ensuring that infections capable of causing TADs are not present in the locality of production, that is, if these infections do not occur in the locality of production, they cannot be spread by commodities sourced there. This geographic approach on the part of the TAHC is progressively being supplemented by the introduction of standards that are not strictly geographic, for example, compartmentalization and lists of commodities that are inherently safe in respect of the diseases covered by individual TAHC chapters (a list of such commodities is provided at the start of some chapters). Article 4.4.3, among others, makes mention of compliance with HACCP principles for identification and management of risks associated with compartments (OIE, 2012a). There are also TAHC articles based at least partially on management of commodity-specific risks, for example, Article 8.5.25 of the TAHC dealing with FMD and deboned beef in countries or zones with an official FMD control programme involving comprehensive systematic vaccination (OIE, 2012a). The TAHC also accepts that heating of commodities of animal origin may be used to destroy TADs-causing pathogens, the standards being included in some disease chapters, for example Chapter 8.5 (OIE, 2012a). However, effects of complex processing procedures other than heating or salting and drying are not covered by the TAHC (Thomson et al., 2004).

Hazard analysis critical control points is defined as a system which identifies, evaluates and controls hazards that are significant for food safety; the five preliminary steps and seven basic 'principles' are provided by FAO/WHO (2003). Thomson et al. (2013) have provided a working definition for CBT.

A further difference between CA and TAHC standards is that the latter essentially apply 'up to the farm gate', while CA standards are pertinent to products and their manufacturing procedures 'after the farm gate'. However, the CA deals exclusively with agents potentially harmful to people and so does not provide standards for products in respect of non-zoonotic animal infections. The OIE, on the other hand, does not provide standards for animal disease risk management associated with complex manufacturing processes. As a consequence, and while the OIE and CAC liaise regularly to overcome such inconsistencies, there remains an important gap in the international standards continuum (Thomson et al., 2004).

Apart from international standards that have been developed by the relevant ISSBs to support the SPS Agreement, many other standards, especially for food safety and various other forms of quality assurance for food products, have been formulated by a variety of organizations, for example the International Standards Organization (including ISO 22000, a food safety management system), transnational food companies, supermarkets, retail consortia and producer organizations (Stanton and Wolff, 2008; Hammoudi et al., 2009). Such standards are usually collectively referred to as private standards and are commonly linked with associated or independent certification organizations/systems. Almost all private standards associated with food products adopt the HACCP approach. Furthermore, it is well recognized that risk management is best assured by 'good practice' along the entire production process, such as good agricultural practice (e.g. GlobalGAP – http://www.globalgap.org/uk_en/) and good manufacturing practice (GMP). This is encapsulated by catch phrases like 'farm to fork' and 'stable to table'.

Quite different matters are also becoming important in determining access to markets where traders need to provide products that accord with their customers' requirements for quality, taste and social and environmental equity. Animal welfare, welfare of producers and farm workers, social and environmental effects of livestock farming (e.g. greenhouse gas generation by intensively farmed livestock and the carbon footprint of long-distance transport of food products), as well as the indirect effects of expanding production on land use and biodiversity in developing regions, are all beginning to influence trade in foodstuffs and their constituents (World Bank, 2009; Gómez et al., 2011). Such requirements, depending on the product and the target market, will increasingly need to be considered in the context of trade standards and may have an influence on how disease risks are managed and the acceptability of certain types of products. This is recognized by ISSBs although the relationship between international and private standards is convoluted (see http://www.oie.int/fileadmin/Home/eng/Internatiional_Standard_Setting/docs/pdf/A_RESO_2010_PS.pdf).

Modern food production processes increasingly involve sequential procedures, usually collectively referred to as the value chain because each step contributes value. The management of risks of various types, not exclusively related to food safety and animal diseases, is necessary along the entire value chain, that is, from the raw material (e.g. animals in the field and what they are fed and how they are managed) to the finished, packaged product on the supermarket shelf (Official Journal of the European Union, 2003b; FAO, 2011; Gómez et al., 2011). There are many definitions for value chains, to some extent dependent on whether they are viewed from a narrow (i.e. within a particular enterprise) or broader perspective. From the broader perspective, adopted for this discussion, value chains constitute the complex range of activities implemented by various actors (primary producers, processors, traders and service providers) to transform raw material via a production chain into the saleable final commodity or product (FAO, 2011).

Potential Integration of Sanitary Risk Management Systems for Infectious Agents Along Value Chains

A variety of proven risk amelioration methodologies can potentially be employed in the management of risk along value chains to ensure sanitary safety, including their use in combination. The CA adopts HACCP as the major methodological approach, while the TAHC generally accepts three different systems applicable in different circumstances. Major features of these four methodologies are summarized in Table 1. This dichotomy of methodology makes the achievement of integrated food safety and animal disease management along value chains difficult.

As initially envisaged, CBT was aimed primarily at identification of animal commodities that are inherently 'safe' in terms of specific sanitary risks. A good example is milk derived from cows suffering from BSE; available evidence indicates that the BSE agent is not present in infectious quantities in the milk of diseased cows (Everest et al., 2006). Likewise, deboned and properly matured beef from which visible lymph nodes have been removed is considered to present a 'very low' risk of transmitting BSE, FMD and several other infectious agents (Thomson et al., 2009; Paton et al., 2010). However, it was equally evident when CBT was first proposed as a practical approach that additional processing of raw commodities could further mitigate the probability of products being able to transmit infectious agents (Thomson et al., 2004; OIE, 2012b). It needs to be added that acceptance of processing does not imply that commodities derived from diseased animals can be transformed into products for human consumption; quite the contrary, because only tissues and secretions of healthy animals are acceptable in the human food chain.

In publications on the application of CBT as a means of providing an alternative to geographic risk management standards associated with trade in commodities and products of animal origin, the similarity in concept, and therefore potential for integration, of HACCP and CBT methodologies was not investigated (Thomson et al., 2004, 2006, 2009; Paton et al., 2010; Rich and Perry, 2011). However, perusal of their similarities/dissimilarities indicates remarkable commonality. Both HACCP and CBT are essentially based on (i) identification of the hazards associated with a particular commodity or product/process, (ii) identification and selection of appropriate risk mitigation measures (where potentially a variety are available and, also, multiple barriers obviously provide additional protection), (iii) application of one or more of the identified risk management options and (iv) assurance that the mitigation measures have been effectively applied so that the traded commodity or product can be accepted as having appropriate (i.e. acceptably low) risk by the importer and competent authority of the importing country. The identification and management of critical control points (CCPs) and compliance with the limits set for individual CCPs constitute a crucial attribute of HACCP. Focusing value chain monitoring and control on CCPs with associated recording therefore provides a practical basis for efficient auditing and certification.

We consequently contend that HACCP and CBT approaches are eminently amenable to integration for management of both food safety and animal disease hazards along value chains. An example is presented in Fig. 1.

Table 1. Semi-quantitative assessment of the features of different risk management mechanisms associated with trade in commodities and products derived from animals (viewed from the perspective of FMD control)

Method	Benefits / costs focused on participants in livestock trade	Potential for significant adverse socio-economic & environmental impact	Requirement for significant investment		Complements complex processing	Amenable to routine auditing	Promotion of product traceability
			Public sector	Private sector			
HACCP (CA)	+++	–	+	+++	+++	+++	+++
CBT (TAHC)	+++	–	+	+++	+++	++	+++
Compartmentalization (TAHC)	+++	+	+	+++	++	++	++
Country- or zonal freedom from infection (TAHC)	+	+++	+++	++	–	–	+

CA, Codex Alimentarius; TAHC, Terrestrial Animal Health Code; HACCP, hazard analysis, critical control points; CBT, commodity-based trade; CCP, critical control points.
–: no effect; +: little effect; ++: intermediate effect; +++: marked effect.

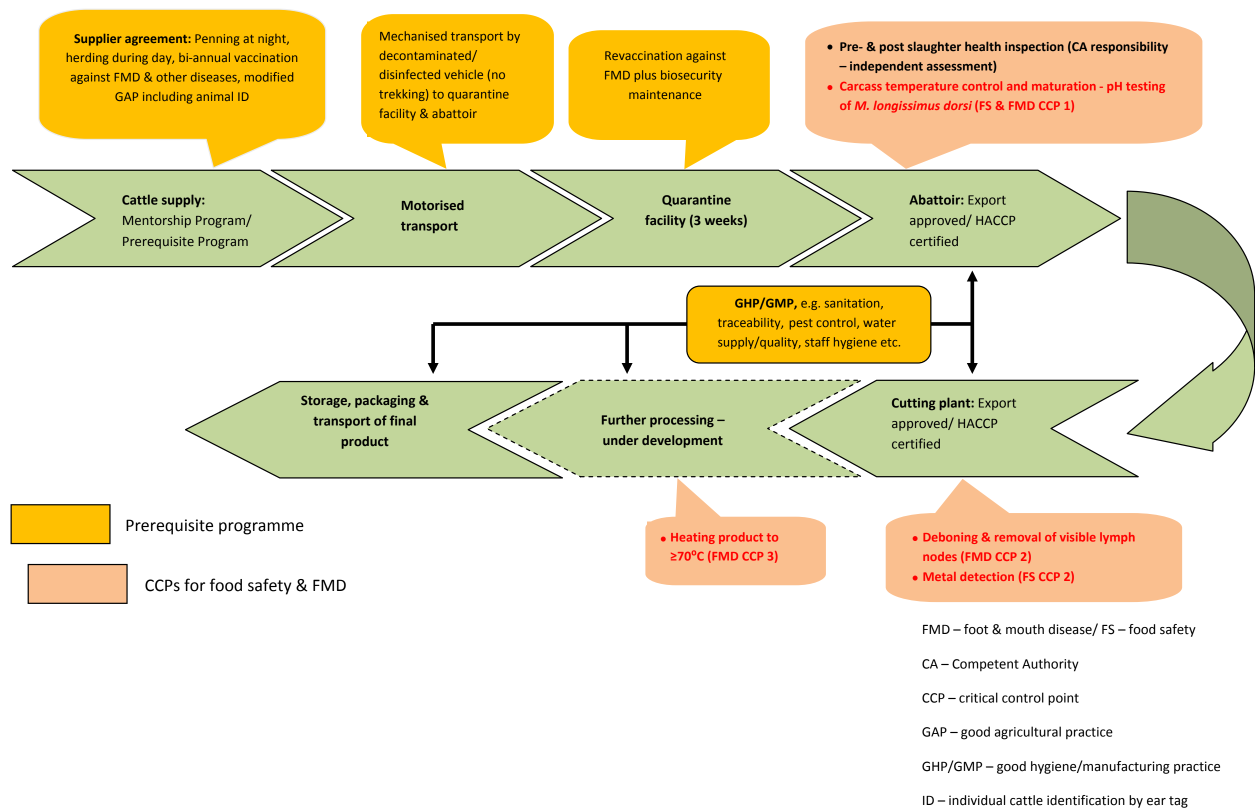

Fig. 1. Proposed value chain management for beef and beef product export from the Zambezi Region[2], Namibia (a region not recognised as free from FMD), incorporating critical control points (CCPs) for management of FMD risk (i.e. CCPs additional to those for managing food safety risks) as well as hygiene and other risk management prerequisites.

Auditing and Certification

Food safety certification is essential to support international trade in commodities and products derived from animals and, despite considerable regional and national variation, is well established through networks of statutory agencies acting on behalf of competent authorities, delegated accreditation bodies and companies authorized to train, audit and certify companies engaged in food production and trade. Most food safety certification, if not all, is based on HACCP systems. When it comes to auditing and certification of exports of animal origin in respect of TADs, all actions and authority including certification lie (if OIE recommendations, as the animal health standard-setting body for the WTO SPS Agreement, are followed) within the ambit of the veterinary authority of the exporting country concerned (Articles 5.1 & 5.2, OIE, 2012a). In the opinion of the authors, these standards are currently predominantly geographic in nature.

Equivalence of standards is a matter for bilateral negotiation and agreement between trading countries, that is, not set by ISSBs. Due to the limited availability of exclusively commodity-specific standards in the TAHC, it is unsurprising that equivalence related to TADs risk management has so far not been a feature of international trade in animal commodities and products, although agreements in this respect have been reached between developed countries with significant technical and administrative capacity (e.g. between the EU & USA, Official Journal of the European Union, 2003a). So, while equivalence provides clear opportunity for facilitation of trade, in practice the requirements and procedures are ill-defined, expensive, time-consuming and potentially convoluted (OIE, 2012a).

It has previously been pointed out that developing countries particularly suffer from their certification procedures lacking credibility (Thomson et al., 2006). Presumably for that reason, major importers (e.g. EU and USA) often perform their own inspections. Currently, such inspection, in line with the TAHC, appears to concentrate primarily upon ensuring that designated TADs are not present in the locality of origin irrespective of the final product.

When it comes to auditing and certifying value chains in respect of animal disease risks, however, guidelines and procedures are lacking despite the fact that CBT is accepted in principle by the OIE. This situation is especially problematic for developing countries where the veterinary authorities (i.e. official veterinary services) often do not have the workforce, structure or skills to perform such functions reliably. Therefore, as argued previously, new approaches to auditing and certification, with accompanying guidelines, are needed, particularly for management of TADs risks along value chains (Thomson et al., 2006). The FAO has provided a guideline on animal disease risk management along value chains but that guideline does not address the issue of certification (FAO, 2011). Unless credible certification systems, ideally provided by independent (i.e. third party) organizations that specialize in certification and have the capacity to act on behalf of governments in that respect can be introduced, development of value chain risk management in respect of animal infections will not progress satisfactorily. For third party-certification to be practically implementable, provision of appropriate standards and guidelines is a prerequisite.

An Example of an Integrated Value Chain Approach Incorporating Aspects of HACCP and CBT

In an attempt to demonstrate how HACCP and CBT approaches can be integrated to manage FMD risk associated with beef production in an area where the SAT serotypes of FMD virus are endemic in free-ranging African buffalo (*Syncerus caffer*), a project is in progress in the Zambezi Region of Namibia (Millennium Challenge Account Namibia, 2010). The details of the project are not presented here, but Fig. 1 outlines the sanitary risk mitigation measures for FMD management along the beef value chain with CCPs indicated (there are CCPs for both food safety and FMD risk management). Management of the FMD risk for this value chain (required by Namibia's competent authority, i.e. over and above recommendations in Article 8.5.25 of the TAHC [OIE, 2012a] that deals with the export of deboned beef from countries or zones not recognised as free from FMD but with an official FMD control programme involving compulsory systemic vaccination), incorporates additional measures that are part of the prerequisite programme. This results in a multiple-barrier system for the management of FMD risk.

The risk mitigation process for FMD involves the following: (i) management of cattle in the field to minimize the risk of FMD infection by herding animals away from locations that wildlife frequent, as well as mass bi- or tri-annual vaccination against FMD (the latter conducted by the official veterinary service – clause 1.c of Article 8.5.25 of the TAHC), (ii) motorized transport to the quarantine facility (i.e. avoidance of trekking of cattle which was a feature of the system hitherto – clause 1.e), (iii) 3-week quarantine of all slaughter cattle in a government-owned and managed quarantine facility during which revaccination of cattle against FMD is conducted, with physical inspection of all cattle entering and leaving the quarantine station (not a requirement of Article 8.5.25), (iv) direct motorized transport to the abattoir and further *ante-* and *post-mortem* inspection of all slaughter cattle (clauses 1.e & 1.g), (v) deboning of the beef and removal of visible lymph nodes (clause 2.a), (vi) testing of the longissimus dorsi muscle pH 24 h after slaughter to ensure it is below 6.0 (clause 2.b), (vii) further quarantine of the beef in cold storage (to allow for detection of a potential FMD outbreak during that 3-week period, before product is released, and not a requirement of Article 8.5.25).

Critical control points for FMD risk management are indicated in Fig. 1, but these are being further assessed using risk and sensitivity analysis based on data that are being generated by the study. For investigative purposes, additional measures are being implemented comprising (i) serological monitoring of slaughtered animals to verify their immune status using a DIVA (differentiating infected animals from vaccinated animals) system and (ii) scanning of selected lymph nodes from slaughtered cattle by PCR to identify FMD viruses possibly present in subclinically infected cattle derived from high-risk areas.

Using this approach, sequential barriers against the presence of FMD virus at critical stages along the value chain will be created together with appropriate monitoring of CCPs to enable technical documentation and auditing. It is possible that further processing of the deboned beef may be adopted as an additional risk mitigation (by heating to ≥70°C) and value-adding measure (Article 8.5.34 of the TAHC).

The abattoir concerned in the Zambezi Region was registered to export deboned beef to South Africa, but exports of chilled and frozen deboned beef were stopped after the FMD outbreak in Zambezi Region in 2008.

It is anticipated that formal risk assessments based on data provided by the study will show that redundancy among these risk mitigation measures exists and therefore it is anticipated that the system can be simplified, because the process described above is too complicated and expensive to be practical or profitable on a routine basis. It should be noted that socio-economic and environmental studies have shown that an integrated approach has clear advantages over the existing system as well as over other possible alternatives (Barnes, 2013; Cassidy et al., 2013).

We contend that the approach outlined above overcomes a fundamental problem created for southern African countries by clause 1.d of Article 8.5.25 which requires certification that FMD has not occurred within 10 km of the establishment of origin in the 30 days prior to slaughter. This is practically impossible to prove bearing in mind that subclinical infection of wildlife occurs in southern Africa (Thomson et al., 2013).

Discussion

The potential application of HACCP-based approaches to management of animal disease-associated trade risks is frequently confounded by the perception that HACCP is (i) exclusively a food safety tool and (ii) applicable only to specific enterprises such as abattoirs or meat processing plants but not more broadly to, for example, complex value chains. This is clearly not the case because HACCP involves an inherently logical model applicable to many manufacturing processes where quality assurance is vital, including within the pharmaceutical and cosmetic industries. Just as value chains may be viewed in narrow or broader contexts (see above), the same applies to HACCP. Implementation of CBT is likewise applicable at various points along value chains (Thomson et al., 2004, 2009; Scoones et al., 2010).

What is novel in the scenario presented here is integration of commodity-specific measures based on the CBT concept and HACCP. Some of these measures are already incorporated into the TAHC, but the advantage provided by CCPs to facilitate management of animal health risks along value chains is not. The employment of CCPs for value chain management provides a proven and practical mechanism for implementation, auditing and certification. Clear guidelines and standards in this respect are needed for risk management related to animal infections and can only be provided by the relevant ISSB. It is appreciated that although this process is superficially straightforward, in practice, even in the food manufacturing sector of developed countries, application of HACCP faces difficulties especially where medium-sized or small businesses are concerned (Herath and Henson, 2010).

The changes in approach and process advocated above are particularly pertinent in the light of the recently launched Global Strategy for the Control of FMD and the Progressive Control Pathway for Foot and Mouth Disease (PCP-FMD) that are being driven by the OIE and FAO (FAO, 2012; OIE, 2012c). An issue in that regard is the emphasis on geographic approaches to FMD management, although non-geographic possibilities are mentioned. There is consequently a need to further develop non-geographic standards and auditing processes to facilitate their implementation. To be practical, the standards need to be applicable across the variety of epidemiological situations related to FMD that occur globally, including accommodation of difficulties posed by FMD at the livestock/wildlife interface in southern Africa, a situation that the OIE and FAO are also starting to acknowledge merits attention (see Resolutions: FAO/OIE Global Conference on FMD Control, Bangkok, Thailand 27–29 June 2012 – www.oie.int).

The above does not by any means imply that effective management of TADs is not vital; quite the contrary. Unhealthy animal populations render animal production inefficient and inadequate to support local trade, much less export industries targeting high value markets where food safety and quality are paramount. Making access to international markets more practically achievable for developing countries would provide an incentive for investments in animal agriculture and more effective approaches to animal disease control, especially in arid regions with significant wildlife populations. In southern Africa, expanded access to international markets via non-geographic approaches could also help to resolve the heretofore intransigent conflict between the wildlife conservation and livestock agriculture sectors (Osofsky, 2010; Thomson et al., 2013).

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Note

[1]In this paper, *commodities* are live animals and their derivatives that have not undergone further processing, that is, raw meat, milk, eggs and raw hides. *Products* have undergone further processing that may or may not mitigate the risk of their containing pathogens.

[2]The name of the Caprivi has recently been changed by the Namibian Government to 'Zambezi Region'.

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