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Policy-driven development of cost-effective, risk-based surveillance strategies

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ABSTRACT

Animal health and residue surveillance verifies the good health status of the animal population, thereby supporting international free trade of animals and animal products. However, active surveillance is costly and time-consuming. The development of cost-effective tools for animal health and food hazard surveillance is therefore a priority for decision-makers in the field of veterinary public health. The assumption of this paper is that outcome-based formulation of standards, legislation leaving room for risk-based approaches and close collaboration and a mutual understanding and exchange between scientists and policy makers are essential for cost-effective surveillance. We illustrate this using the following examples: (i) a risk-based sample size calculation for surveys to substantiate freedom from diseases/infection, (ii) a cost-effective national surveillance system for Bluetongue using scenario tree modelling and (iii) a framework for risk-based residue monitoring. Surveys to substantiate freedom from infectious bovine rhinotracheitis and enzootic bovine leucosis between 2002 and 2009 saved over 6 million € by applying a risk-based sample size calculation approach, and by taking into account prior information from repeated surveys. An open, progressive policy making process stimulates research and science to develop risk-based and cost-efficient survey methodologies. Early involvement of policy makers in scientific developments facilitates implementation of new findings and full exploitation of benefits for producers and consumers.

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1. Introduction

The global annual export value of agricultural products – most of which is food – is estimated to be over US$ 1000 billion. Almost all countries participate in international food trade – most of them being both importers and exporters, resulting in complex trade patterns (Stärk, 2010). International trade is regulated by the World Trade Organisation (WTO). One of the founding agreements of the WTO was the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which specified rules for animal and plant health standards and food safety. The respective standards are developed by the Codex Alimentarius Commission (CAC), the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC). The main aim of the SPS agreement is to facilitate trade in agricultural products while allowing countries to protect human, animal and plant health status. Countries can require sanitary measures for exotic diseases or those under official domestic control programmes. This calls for the use of well-designed surveillance systems with a valid scientific basis in order to demonstrate control efforts or absence of disease.

The most important trading partner for Switzerland is the European Union (EU). Trade in agricultural products is regulated in the Agreement on trade in agricultural

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products, in force since 2002 (Anonymous, 2002). Annex 11 to this agreement addresses sanitary measures applicable to trade in live animals and animal products. The objective is to facilitate trade by establishing a mechanism for the reciprocal recognition of the equivalence of legislation consistent with the protection of public and animal health. By decision of the Joint Veterinary Committee, veterinary border checks between the EU and Switzerland were abolished at the end of 2008. This created a common veterinary area and seamless trading conditions in the veterinary field.

Annex 11 determines also the mandatory surveillance and monitoring programmes and either directly specifies their technical application or refers to the relevant EU regulatory guidelines and directives. In 2008, 15 of Switzerland's 17 nationally coordinated animal health surveillance and food residue monitoring programmes had to be conducted according to EU animal health and food safety regulations.

Maintaining so many monitoring and surveillance programmes at high levels of technical specification with respect to confidence, detection level, accuracy and representativeness is time consuming and expensive. This contrasts with the declining human and financial resources accessible to government veterinary services in many countries world-wide. For documentation of freedom from disease at a low prevalence threshold and for estimation of prevalence with high accuracy, very large surveys are needed. For such purposes, risk-based surveillance is particularly beneficial. However, the additional resources required in the design of risk-based surveillance need to be balanced against the savings made through its smaller sample sizes (Stärk et al., 2006). Risk-based approaches are also emerging in the design of other resource-demanding activities such as inspections and animal health interventions such as vaccination.

International publications issued by the OIE, CAC and Food and Agriculture Organisation (FAO) refer to risk-based methods. The concept can therefore be considered internationally accepted and applicable in a variety of contexts. Risk-based surveillance is also encouraged by the European Union, whereby member states are asked to apply a risk-based approach when designing various programmes for the monitoring of food safety and animal health. For example, a risk-based approach was required for the monitoring of the safety of milk and milk products as well as for the surveillance of avian influenza and bluetongue virus infection. The absence of a clear definition of the term "risk-based approach" has led to different interpretations and confusion (Stärk et al., 2006). Considerable heterogeneity exists among programmes in terms of approach and openness of methodologies formulated in associated EU directives. While some programmes are increasingly becoming outcome-based with only confidence and threshold prevalence levels being defined, others have to follow inflexible guidelines and fixed sample schemes.

This paper aims to describe policies which either constrain or promote the evolution of cost-effective surveillance schemes. Examples of policies which stimulate science to develop new risk-based approaches and veterinary services to implement them are compared with these which are less flexible or even rigid.

2. Methodology

The following monitoring and surveillance programmes are described and analysed with respect to (i) the degree of flexibility in requirements concerning design and formulation of targets to be achieved such as attaining a certain confidence or sampling a certain percentage of the population, (ii) room for risk-based approaches in the legislation and (iii) exchanges among scientists, veterinary services and policy makers while researching, developing, legislating and implementing the programmes:

- Surveys to substantiate freedom from infectious bovine rhinotracheitis (IBR) and enzootic bovine leucosis (EBL) in accordance with the bilateral agreement between Switzerland and the EU on trade in agricultural products (Anonymous, 2002).
- Bluetongue (BT) surveillance in accordance with commission regulation 1266/2007 on implementing rules for Council Directive 2000/75/EC regarding the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue (Anonymous, 2007).
- National residue monitoring programme in accordance with the Council Directive 96/23/EC (Anonymous, 1996).

The hypothesis of this paper was that each of the following criteria is essential for a successful development and implementation of cost-effective monitoring and surveillance programmes: (i) outcome-based formulation of standards, (ii) legislation leaving room for risk-based approaches and (iii) close collaboration and mutual understanding and exchange between scientists and policy makers.

The three examples were chosen to illustrate the benefit that can be achieved with respect to cost-effectiveness (surveys to substantiate freedom from IBR and EBL) and cost-effectiveness plus timeliness (BT surveillance) via the implementation of risk-based surveillance systems if all of the above mentioned criteria are fulfilled. The residue monitoring example was chosen to illustrates that efficacy of a programme is not attained – neither by achieving goals with fewer resources nor enhancing confidence and safety with existing ones – if only the criterion on close collaboration between researchers and policy makers in researching and developing new programmes is met, but higher-ranking legislation does not allow for outcome-based formulation of requirements and risk-based sampling.

To better understand the different general conditions under which the three programmes were developed and implemented and to elucidate why designing and implementing risk-based survey methodology was a declared goal, the history of each programme is given below.

2.1. Surveys to substantiate freedom from IBR and EBL

Both IBR and EBL have been eradicated in Switzerland. To substantiate freedom from these two diseases, annual

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