

BEST PRACTICES

for risk-based and cost effective
animal health surveillance
in the European Union



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TABLE OF CONTENTS

| | |
|---|----|
| Index of Best Practice Examples | 3 |
| Foreword..... | 4 |
| List of authors & contributors..... | 6 |
| 1 About this document..... | 6 |
| 1.1 Scope..... | 6 |
| 1.2 Target audience | 6 |
| 1.3 Recommended use | 6 |
| 1.4 Acknowledgements..... | 8 |
| 1.5 Toolbox 1..... | 9 |
| 2 Terminology..... | 10 |
| 2.1 General definitions..... | 10 |
| 2.2 Definitions related to risk-based surveillance | 11 |
| 2.3 Definitions related to cost-effectiveness and evaluation of efficiency | 12 |
| 2.4 Toolbox 2..... | 13 |
| 3 Prioritisation..... | 14 |
| 3.1 Drivers, funders and constraints..... | 14 |
| 3.2 Policy purpose..... | 16 |
| 3.3 Development of a prioritisation model | 17 |
| 3.4 Involving Stakeholders..... | 21 |
| 3.5 Toolbox 3..... | 23 |
| 4 Planning..... | 24 |
| 4.1 Surveillance objectives..... | 24 |
| 4.1.1 Single objective surveillance | 24 |
| 4.1.2 Multi-objective and multi-hazard surveillance | 26 |
| 4.2 From surveillance to intervention measures..... | 28 |
| 4.3 Documentation, working protocols and templates..... | 30 |
| 4.4 Toolbox 4..... | 32 |
| 5 Risk-based Design..... | 33 |
| 5.1 General considerations | 33 |
| 5.1.1 Case definitions..... | 33 |
| 5.1.2 Surveillance components..... | 34 |
| 5.1.3 Risk factors..... | 34 |
| 5.1.4 Risk-based surveillance | 35 |
| 5.1.5 Disadvantage of risk-based surveillance..... | 35 |
| 5.2 Design considerations by surveillance objective | 35 |
| 5.2.1 <i>Absent diseases</i> - Early detection of the incursion of new, (re)-emerging or exotic diseases | 35 |
| 5.2.2 <i>Absent diseases</i> - Demonstrating freedom from disease (or pathogens) | 38 |
| 5.2.3 <i>Present diseases</i> - Describing the level of disease occurrence | 42 |
| 5.2.4 <i>Present diseases</i> - Detecting cases of disease..... | 48 |
| 5.3 Toolbox 5..... | 53 |
| 6 Implementation..... | 56 |
| 6.1 Roles and Responsibilities..... | 56 |
| 6.2 Training and raising awareness..... | 57 |
| 6.3 Data management and Information system..... | 58 |
| 6.4 Reporting and information dissemination..... | 59 |

| | | |
|-------|---|-----|
| 6.5 | Toolbox 6..... | 61 |
| 7 | Evaluation and performance monitoring..... | 62 |
| 7.1 | Objectives..... | 62 |
| 7.2 | Performance monitoring..... | 65 |
| 7.2.1 | Planning..... | 65 |
| 7.2.1 | Selection of performance indicators..... | 66 |
| 7.2.2 | Implementation of performance monitoring..... | 67 |
| 7.3 | Evaluation..... | 68 |
| 7.3.1 | Planning..... | 68 |
| 7.3.2 | Elements of evaluation..... | 69 |
| 7.3.3 | Level of evaluation..... | 74 |
| 7.4 | Limitations by choice of evaluation element(s)..... | 77 |
| 7.5 | Toolbox 7..... | 78 |
| 8 | Economic evaluation..... | 79 |
| 8.1 | Benefits of surveillance..... | 79 |
| 8.1.1 | Disease loss avoidance..... | 79 |
| 8.1.2 | The value of information..... | 81 |
| 8.1.3 | Other benefits..... | 81 |
| 8.2 | Common economic evaluation techniques..... | 84 |
| 8.2.1 | Cost Benefit Analysis..... | 85 |
| 8.2.2 | Cost effectiveness analysis..... | 86 |
| 8.2.3 | Least-cost analysis..... | 86 |
| 8.3 | Quantifying inputs and outcomes (costs and benefits)..... | 87 |
| 8.4 | Toolbox 8..... | 89 |
| 9 | From evaluation to strengthening surveillance..... | 91 |
| 10 | Conclusion..... | 93 |
| | References..... | 94 |
| | Annex A – Design - Best practice examples for Section 5.2.2..... | 99 |
| | Annex B – Economic evaluation..... | 104 |
| | Additional explanation for Figures 20 and 21 (Section 8.1.1)..... | 104 |
| | Detailed explanation of economic evaluation techniques (Section 8.2)..... | 104 |
| | Cost Benefit Analysis (CBA)..... | 105 |
| | Cost Effectiveness Analysis (CEA)..... | 107 |
| | Least-cost analysis (LCA)..... | 109 |

INDEX OF BEST PRACTICE EXAMPLES

| | |
|--|----|
| Best Practice Example 1. The Danish model..... | 15 |
| Best Practice Example 2. The Swedish prioritisation process..... | 20 |
| Best Practice Example 3. Step 1: The scope of prioritisation | 20 |
| Best Practice Example 4. Step 1: Scaling the criteria for prioritisation | 21 |
| Best Practice Example 5. Participation of stakeholders..... | 22 |
| Best Practice Example 6. SWOT for stakeholder engagement | 23 |
| Best Practice Example 7. The Swedish animal health surveillance system | 27 |
| Best Practice Example 8. Risk communication today | 30 |
| Best Practice Example 9. Detection of Rift Valley fever in ruminants in suitable vector climate | 38 |
| Best Practice Example 10. Risk-based sampling | 38 |
| Best Practice Example 11. Combination of evidence from multiple components | 38 |
| Best Practice Example 12. Risk-based requirement to calculate sample size | 38 |
| Best Practice Example 13. Risk-based requirement to calculate probability of freedom | 38 |
| Best Practice Example 14. Representative sampling | 44 |
| Best Practice Example 15. Making inference from high-risk group to population: the point value | 46 |
| Best Practice Example 16. Representative sample versus risk-based sample..... | 47 |
| Best Practice Example 17. High-risk strata | 52 |
| Best Practice Example 18. Low-risk strata | 52 |
| Best Practice Example 19. Federal food safety and veterinary office (FSVO, Bern, Switzerland) | 56 |
| Best Practice Example 20. Some european projects that produced training material | 58 |
| Best Practice Example 21. Quarterly reporting in the Netherlands | 61 |
| Best Practice Example 22. Stakeholders selecting performance indicators | 66 |
| Best Practice Example 23. Performance (or quality) indicators for passive surveillance in the Netherlands..... | 67 |
| Best Practice Example 24. Participatory toolbox for the evaluation of acceptability (AccEPT) | 70 |
| Best Practice Example 25. AccEPT method for classical swine fever surveillance in wild boar in Germany..... | 71 |
| Best Practice Example 26. AccEPT method for the bovine tuberculosis surveillance in Belgium | 72 |
| Best Practice Example 27. Evaluation of effectiveness of the CSF surveillance in wild boar in Germany.. | 73 |
| Best Practice Example 28. Evaluation of the value of animal health information | 83 |
| Best Practice Example 29. Cost benefit analysis of classical swine fever surveillance in the Netherlands..... | 85 |

FOREWORD

The global demand for sufficient, safe and nutritious food will continue to increase, and require further intensification of livestock production, while at the same time recognising the need to protect our environment. The resulting eco-social changes will increase the risk of emergence and spread of new and known infectious diseases affecting animals and humans. These developments will increase the need to conduct effective disease surveillance, which also has to be more cost-effective than currently given the reduced availability of financial resources. *This means that knowledge about variation in disease risk in populations-at-risk will be required, so that animal health surveillance effort can be structured such that timely and maximum sensitivity of detection can be achieved while still being cost-effective.* The development of such surveillance systems is technically more challenging, and requires an approach to the process that is based on the most up-to-date knowledge effectively integrated between different scientific disciplines and transparent to stakeholders. It also needs to be recognised that design of risk-based surveillance systems will usually involve a process of comparing several options, which ideally should include a formal evaluation component. *As a result, the process of risk-based surveillance design is associated with more advanced technical and interdisciplinary skills than traditional surveillance.* To enable widespread acceptance and adoption of these risk-based surveillance systems it is essential to provide developers with science-based frameworks guiding them through the process of design as well as evaluation.

THE RISKSUR PROJECT has addressed this particular need. The project was conducted between 2012 and 2015, funded by the Seventh Framework Programme (FP7) of the European Union. It has developed decision support tools for the design and evaluation of cost-effective risk-based surveillance systems for animal health. Coordinated by Professor Dirk Pfeiffer from the Royal Veterinary College, London, United Kingdom, the Consortium involved 11 European partners and the Food and Agricultural Organization of the United Nations (FAO), bringing together scientific expertise in veterinary medicine, veterinary epidemiology, statistical analysis, surveillance, risk assessment and animal health economics (Figure 1).

The RISKSUR Consortium

Acceloment AG (Switzerland)
Animal and Plant Health Agency (United Kingdom)
Arcadia International E.E.I.G. (Belgium)
CIRAD/Agricultural Research for Development (France)
Complutense University of Madrid (Spain)
Food and Agriculture Organization of the United Nations (Italy)
Friedrich-Löffler-Institut (Germany)
GD-Animal Health (the Netherlands)
Royal Veterinary College London (United Kingdom)
SAFOSO (Switzerland)
The Swedish National Veterinary Institute (Sweden)
TraceTracker AS (Norway)

Figure 1. The RISKSUR consortium

Focussing on **FOUR SURVEILLANCE OBJECTIVES** (Figure 2), RISKSUR has integrated its generated outputs into a freely available online tool to support decision making and its' documentation for the design and evaluation of risk-based surveillance: the Surveillance Design Framework and the EVA (evaluation) Tool.



Figure 2. The four animal health surveillance objectives that the RISKSUR project focussed its activities on

The rules specified in the new Animal Health Law of the European Union will have to be implemented gradually over the next 5 years (http://ec.europa.eu/food/animal/animal-health-proposal-2013_en.htm). It will be less complex than previous legislation and provide more flexibility for each Member State to adapt their risk management to variation in risk within their particular production system and social context. An essential component will be animal health surveillance systems that effectively integrate different surveillance components aimed at single or multiple diseases. The frameworks and tools developed by the RISKSUR project are ideally suited for developing such systems as well as for generating standardised documentation that allows transparent communication amongst different stakeholder groups.

Furthermore, RISKSUR looked into available guiding documents for surveillance of infectious diseases relevant to livestock. The RISKSUR consortium reviewed those guiding documents and consulted 42 animal health surveillance professionals from the European Union over a **BEST PRACTICES WORKSHOP** in September 2014, to identify the documents' strengths, weaknesses, opportunities and threats. They identified a gap in the existence of a guiding document that addresses the design and evaluation of risk-based animal health surveillance for all four objectives, which can be used to take informed decisions *for practical applications in real-life circumstances*. Hence this best practices document came about.

Under the title of **BEST PRACTICES** this document aims to coherently link the work carried out by RISKSUR with other relevant resources and to present good working examples, with the aim to guide the decision-making process on design and evaluation of risk-based animal health surveillance towards cost-effective solutions.

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1 ABOUT THIS DOCUMENT

1.1 SCOPE

This document intends to be a practical resource to assist users while going through the different stages of the process of designing, implementing and evaluating a cost-effective animal health surveillance system, particularly if it is risk-based. The document should help the reader to locate information already available and use the presented best practice examples to (re)-design efficient surveillance systems. The document's main focus is on risk-based animal health surveillance and cost-effective solutions for diseases relevant to livestock in the European Union.

1.2 TARGET AUDIENCE

This document was written for **COMPETENT AND TECHNICAL LEVEL USERS** who design, implement or evaluate animal health surveillance strategies related to livestock within the European Union. Readers of this document are expected to be epidemiologists, microbiologists, statisticians and economists, working for national authorities and private bodies. Instead of operating individually, it is most likely that readers will work as a team that covers all necessary skills.

The document will also provide support to **DECISION-MAKERS** who can find here a range of best practices as examples of, and a general description of the process and stages for designing and implementing risk-based surveillance systems.

1.3 RECOMMENDED USE

Figure 3 provides an **OVERVIEW** of the cycle associated with cost-effectively managing any animal health surveillance system. The phases include *prioritisation, planning, design, implementation, and monitoring and evaluation*. There are two main managing 'bodies' of surveillance activities: those involved in **POLICY**, where decisions are taken regarding *if* and *what* surveillance activities should be conducted, and those involved in the **TECHNICAL APPLICATION**, where decisions are made regarding *how* surveillance activities should be conducted. Both bodies and their interaction are important throughout the entire cycle, albeit that the emphasis of activities might change depending on the phase. This is shown by the gradient shift in colour of the arrow from orange for policy to blue for technical management.



Figure 3. The phases involved in the process of managing animal health surveillance systems: prioritisation, planning, designing, implementing, monitoring and evaluation. Orange (policy) and blue (technical) parts of the arrow indicate the emphasis on the more dominant management body.

You will recognise the **COLOURED LABELS** from this diagram in the top right corner of every page in chapters 3-8. The labels correspond to those in Figure 3 providing an easy reference to the reader to the systems components Prioritisation, Planning, Design, Implementation, Evaluation and Economic Evaluation.

Chapter 2 on **TERMINOLOGY** precedes the chapters discussing each phase of the cycle, to ensure understanding of terms related to risk-based surveillance and cost-effectiveness by the reader. Where possible, this document applies the **RISKSUR GLOSSARY**, which is publicly available from the RISKSUR website. It contains the terminology and definitions used by those actively involved in animal and public health surveillance and defined through a series of workshops¹ (see ICAHS 2011 final report and Hoinville, 2013). The RISKSUR Glossary is a result of the continuation of this work, through a list of Frequently Asked Questions. Please note that the term *disease* will be used throughout the document, also where only infection with the causing agent is meant, unless indicated otherwise.

Chapters 3 to 8 provide **PRACTICAL EXAMPLES** of **BEST PRACTICE** in separate boxes and **CROSS-REFERENCE** to RISKSUR decision support tools and guidelines, manuals, standards or other resources. At the end of each chapter, there is a **TOOLBOX** with links to tools and documents. A complete list of references is provided at the end of the document.

¹ Workshops in August 2009 related to the International Society for Veterinary Epidemiology and Economics (ISVEE) and in May 2011 related to the International Conference on Animal Health Surveillance (ICAHS)

1.4 ACKNOWLEDGEMENTS

RISKSUR reviewed the available guidelines for animal health surveillance. Several guidelines exist and two major guiding documents were published in 2014:

OIE-GUIDE - In 2014, the OIE published the *Guide to Terrestrial Animal Health Surveillance*. This is a comprehensive general overview of all aspects to be considered when designing and evaluating an animal health surveillance system. It provides a brief introduction to risk-based surveillance and the types of possible risk factors.

FAO-MANUAL - In 2014, the FAO published the *Manual on Risk-Based Disease Surveillance: A manual for veterinarians on the design and analysis of surveillance for demonstration of freedom from disease*. This manual is the result of a worldwide collaborative approach initiated in the year 2000. The manual presents a comprehensive overview of the issues relating to risk-based surveillance for the purpose of demonstrating freedom from disease. It systematically addresses surveillance system characteristics and surveillance options in general and provides clear detailed stepwise guidance on what to take into account and how to build a risk-based surveillance system specifically aiming at demonstrating freedom from disease or early detection of disease incursion.

Starting in the autumn of 2014, the RISKSUR consortium (see Foreword) developed this Best Practices document, with the input from, and revisions by external experts. Building on reviews of existing guidelines, RISKSUR organised a Best Practice Workshop in September 2014 in The Hague, the Netherlands, to gather animal health surveillance professionals from the European Union to discuss the gaps in existing guidance and the possible ways in how to complement these. Subsequently, the Editorial Board of RISKSUR began to integrate best practices, tools and references *to fill one of the identified gaps*, namely the lack of guidance on risk-based animal health surveillance covering all four surveillance objectives and integrating cost-effective solutions.

Input for this document was obtained from:

- RISKSUR experts – See List of authors & contributors
- RISKSUR work-packages:
 - Surveillance design framework – Tools to guide users through the process of surveillance design
 - EVA tool – Tool to formulate specific evaluation questions and evaluate surveillance components
 - Reviews and mapping – Mapped existing surveillance system components and guidance resources
- RISKSUR Best Practice Workshop – 30 September 2014, The Hague, the Netherlands
- RISKSUR Internal review - August 2015 by Gerdien van Schaik (GD-Animal Health, the Netherlands), Katharina Stärk (SAFOSO, Switzerland)
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- Final layout editing: Edina Gallos (Accelopment)

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- Deliverable 7.31 (Annex): Review of surveillance guidelines, <http://www.fp7-risksur.eu/progress/public-deliverables>
- Deliverable 1.1: Mapping, <http://www.fp7-risksur.eu/progress/public-deliverables>
- Website: <http://www.fp7-risksur.eu/progress>
- Glossary: <http://www.fp7-risksur.eu/terminology/glossary>

Hoinville, L., 2013, Animal Health Surveillance Terminology Final Report from Pre-ICAHS Workshop, International Conference on Animal Health Surveillance (ICAHS) - http://www.fp7-risksur.eu/sites/fp7-risksur.eu/files/partner_logos/icahs-workshop-2011_surveillance_terminology_report_V1.2.pdf

2 TERMINOLOGY

2.1 GENERAL DEFINITIONS

| | |
|-------------------------------|--|
| BEST PRACTICE | Working practices, as considered by the members of the RISKSUR project, that are good examples using state-of-the-art methods and approaches under real-life conditions. They can provide practical solutions and approaches. |
| SURVEILLANCE PURPOSE | Describes why surveillance is necessary and what it will accomplish (OIE 2014; RISKSUR FAQs1-4 of "Surveillance purpose"). |
| SURVEILLANCE OBJECTIVE | States those goal(s) that when met will result in the collection and analysis of data in order to achieve the purpose of the system (OIE 2014; RISKSUR FAQs1-4 of "Surveillance purpose"). |
| SURVEILLANCE SYSTEM COMPONENT | Is a single surveillance activity (defined by the source of data and the methods used for its collection) used to investigate the occurrence of one or more hazards in a specified population (RISKSUR FAQs1-4 of "Surveillance purpose"; Hoinville, 2013; for use of this definition in the context of the Surveillance Design Framework see section 2 of Surveillance design framework wikispaces: 2-Surveillance components). |
| PUBLIC-PRIVATE PARTNERSHIPS | A partnership between public and private organisations/actors for carrying out surveillance: this can be by sharing costs, responsibilities and activities and/or benefits. The drivers for public-private partnerships come from questions such as who carries the risk and who harvests the benefits, how responsibilities and costs can be shared, and how cost-effectiveness can be improved by identifying actors who can do a surveillance activity most efficiently given their capacity, experience and resources. |
| CASE | An individual or epidemiological unit identified as having the characteristics of a condition under investigation (Toma, B., 1999 p28) |
| DISEASE CONTROL PROGRAM | On-going operations aimed at reducing the prevalence of a disease in a population to a level where it is no longer considered a major health and/or economic problem. The primary objective is to contain the disease by significantly limiting, if not stopping, its spread to susceptible individuals. Disease control is therefore compatible with the existence of a limited number of cases or outbreaks (Toma, B., 1999 p56) |
| DISEASE ERADICATION PROGRAM | On-going operations aimed at eliminating a disease from a population due to the removal of its cause. Necessary conditions to declare disease eradication include the eliminations of both clinical cases and the pathogen, thus making future cases impossible. The disappearance of the clinical cases due to a vaccine that leaves subclinical infections does not qualify as eradication (Toma, B., 1999 p90). |

2.2 DEFINITIONS RELATED TO RISK-BASED SURVEILLANCE

| | |
|-------------------------|---|
| HAZARD | Any agent that could produce adverse consequences to animal or human health. It is a quantitative (i.e. it can be expressed with a number) characteristic strictly linked to the individual (for example single animal, herd, specific animal species) or entity (for example food product, specific commodity, specific feed batch) under study (OIE Glossary). |
| RISK | The likelihood of the occurrence (probability) and the magnitude of the adverse effects (consequences) to animal or human health, given a specific series of events (scenario) occurring in a specified time period. The risk definition implies that risk is never zero (unless the scenario would not occur) but it can be reduced through the application of control options (OIE Glossary OIE definition). |
| RISK-BASED SURVEILLANCE | The use of information about the probability of occurrence and the magnitude of the biological and/or economic consequence of health hazards, to plan, design and/or interpret the results obtained from surveillance systems. In this definition, risk, similarly to how it is used in the risk analysis field, includes both the probability that a hazard occurs as well as the consequence of occurrence, i.e. it differs from the sometimes more restricted sense used in epidemiology, which refers only to the probability of occurrence (RISKSUR Glossary, based on ICAHS working group report July 2013). |
| RISK FACTORS | <p>The factors that are influencing or are associated with the risk of causing adverse effects (like contracting the infection) in specific subpopulations, or that are protective (“protective factors”) like vaccination. The identification and assessment of such risk factors may derive from different sources:</p> <ul style="list-style-type: none"> • <i>Epidemiological studies</i>: Usually divided into cross-sectional, case-control and cohort studies. • <i>Expert opinion</i>: Methodologies for experts elicitation have been developed that can help in collecting these opinions in a structured way to capture the prevailing understanding of risk factors, despite gaps in documented knowledge. • <i>Risk assessment studies</i>: to provide a more precise estimation of the risk for each subpopulation. <p>Perfect knowledge of the risk factors is not possible, therefore the estimates must take into account a certain level of variability and uncertainty.</p> |

2.3 DEFINITIONS RELATED TO COST-EFFECTIVENESS AND EVALUATION OF EFFICIENCY

| | |
|--|---|
| EVALUATION | Evaluation of one or several surveillance system/component(s) is the determination of its merit by confronting the results of the assessment (see assessment) with standards, targets, criteria or a counterfactual system. Any number of attributes and/or criteria can be considered, depending on the evaluation question. This process <i>shall be transparent, objective and evidence-based</i> . Internal and/or external evaluators can perform an evaluation. Evaluation should lead to a judgment of the system and/or recommendations to strengthen it (RISKSUR terminology workgroup). |
| ASSESSMENT | Assessment of a surveillance system/component is a technical step within the evaluation process, and is the collection and analysis of data on the relevant surveillance attributes and/or criteria (RISKSUR terminology workgroup). |
| TIMING OF EVALUATION | Evaluation can occur at any development stage of a surveillance system: <i>before</i> the start (or <i>ex-ante</i>) evaluation, <i>mid-term</i> (or <i>in itinere</i>) evaluation, <i>terminal</i> evaluation and <i>ex-post</i> evaluation. The focus of the evaluation(-attributes) can slightly differ. Please note that final/terminal evaluations and ex-post evaluations are sometimes treated as synonyms and/or combined in one stage. |
| EFFECTIVENESS/ IMPACT EVALUATION | Evaluation of technical performances of a surveillance system using effectiveness evaluation attributes. Addresses the question: <i>is my system working?</i> |
| ECONOMICS | A discipline concerned with choices about the allocation of scarce resources to satisfy peoples' needs with competing demands: <i>the desired end</i> is achieved by <i>least-cost use of resources</i> , or <i>the probability of achievement of the desired end</i> is <i>maximized</i> under the <i>given amount of resources</i> available. |
| EFFICIENCY | Implies the recognition of <i>scarcity</i> and at the same time the <i>best possible use of resources</i> . |
| PERFORMANCE MONITORING | A day-to-day follow-up of the surveillance system operation using performance indicators (see next), done in a continuous manner and whose results the actors of the system use to adapt the system. |
| PERFORMANCE INDICATORS | A number of variables decided upon during the design stage, allowing calculating continuously the degree of achievements of a surveillance system (component) in order to facilitate daily operational activity management. Performance indicators should be identified by and for the actors of the surveillance systems, in a participatory manner and should be ready at the launch of the surveillance system. |

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3 PRIORITISATION

3.1 DRIVERS, FUNDERS AND CONSTRAINTS

DRIVERS - Animal health surveillance activities are driven by a range of societal needs, such as to quickly detect and manage emerging hazards, to gain acceptance from trade partners, to prevent animal production loss or to protect public health and animal welfare. These needs are expressed through the *policy purpose* of surveillance (see Section 3.2). However, surveillance is only one of many societal needs, and consequently, the allocation of resources to such activities is inevitably a matter of priorities.

The prioritisation process precedes all other phases, and involves assessing and ranking the need for investing in various surveillance activities in order to reach decisions on how to allocate resources to surveillance. Those might lead to investments for improving (an) existing surveillance system(s) or for setting-up (a) new surveillance component(s) or system(s).

Many factors will influence how priorities are being set (see Textbox 1).

Textbox 1

FACTORS INFLUENCING THE NEEDS FOR, AND OUTCOME OF, DISEASE PRIORITISATION - EXAMPLES

- Requirements from international and national legislation
- Changes in the political field (for instance a shift after elections)
- Trade considerations
- Real or perceived concerns about:
 - Emerging threats,
 - Endemic diseases with public health implications,
 - Hazards causing significant welfare issues
 - Hazards causing production loss.

Furthermore, surveillance priorities will change over time, and typically this is driven by changes in the above-mentioned factors. The force of these driving factors will differ depending on perspective – whether it is from the government’s, industries’, communities’ or individual’s points of view. In other words, the relative importance of these driving factors will vary between contexts and stakeholders.

FUNDERS - Another factor in the decision on surveillance priorities is whether the resources to be used are coming from public or private funds, or a combination of the two. For an explanation of public-private partnerships, see Chapter 2. A good practice is to ensure that decisions on whether to do surveillance or not are understood and can be accepted by those concerned. For decision makers who allocate resources for surveillance (i.e. making the “*if*” and “*what*” decisions) this means making the prioritisation process as transparent as possible and to involve all relevant stakeholders (see also section 3.4 Involving stakeholders). The Danish model (see [Best practice example 1](#)) is a good illustration of this.

The mapping of surveillance systems, animal populations, trade flows, critical infrastructure and decision making processes in seven European countries showed that 58% of the mapped surveillance components are 100% publicly funded and 29% are 100% privately funded. For the remaining surveillance components costs were shared. Besides sharing costs (of surveillance and/or intervention costs), the mapping showed a range of active private-public partnerships: joint responsibility for planning, implementation and reporting; shared compensation and/or insurance scheme; data sharing; public service collects and interprets information, stakeholders decide on follow-up. (See RISKSUR Deliverable 1.1 and Annex of RISKSUR Deliverable 7.31; see also the conference proceeding of the 2nd International Conference on Animal Health Surveillance).

CONSTRAINTS - From a national perspective, the freedom to prioritise which hazards to do surveillance for is constrained by priorities determined at a higher, i.e. international level. These may be implemented in international legislation (e.g. by the EU) or codes of conduct (e.g. by the OIE). National needs for surveillance may often coincide with international, but they may also differ. However, the ability for individual countries to influence such international priorities, at least on a shorter term, is usually limited and subject to negotiations and legal processes at high levels of decision-making. Therefore, a regular national decision about whether to do surveillance for internationally prioritised hazards is usually not about “*if*”, but more about “*how*”.

1

In Denmark, there is a tradition for collaboration between veterinary authorities, stakeholders and academia. This is called the Danish model. It implies that the viewpoints of the different stakeholders are presented and discussed **until a compromise or consensus is eventually found**.

This approach has helped in overcoming preliminary disagreements in how to survey and control for various animal health or food safety issues. In fact, the extended collaboration has led to the design and implementation of feasible and cost-effective surveillance and control systems supported economically by the stakeholders.

Moreover, input and further developments have been evidence-based, implying that they have been based on collection of real data – again in many times funded by the stakeholders. Research results originating from various fields have been taken into account, and authorities have been willing to amend the regulations if needed.

In addition, there has been a willingness to implement preliminary actions when judged necessary – and to change the actions when new knowledge became available and pointed in a novel direction. Hence, the approach has both been evidence-based and risk-based.

Best Practice Example 1. The Danish model

3.2 POLICY PURPOSE

The purpose of surveillance describes *why* surveillance is necessary and *what* the surveillance system will accomplish (see Table 1 for examples of surveillance purpose categories: *what* it will accomplish; See also Section 4.2 for the mitigation stages). Surveillance purpose has a more global meaning compared to surveillance objective (see Chapter 2 and Section 4.1). Hence, the *surveillance purpose* should depend on the outputs needed to support decision-making and thus be policy-driven. It should describe *why* surveillance is necessary, and how, when combined with intervention measures, it will impact on public health, animal health and/or the economy (See Table 2). In contrast, the *surveillance objective* refers to the specific goal(s) to be met when collecting the data. More information on formulation of the policy purpose can be found in the RISKSUR Frequently Asked Questions 1 to 4 of Topic 2.1 Surveillance purpose versus objective (see RISKSUR website).

Table 1. Examples of surveillance purposes (what it will accomplish) and mitigation stage (see Section 4.2) of a hazard (adapted from figure in RISKSUR FAQs 1 to 4 for topic 2.1)

| SURVEILLANCE PURPOSE | MITIGATION STAGE |
|---|-------------------------------|
| To confirm disease status | Implementation or Sustainment |
| To identify changes in disease status to facilitate early response | Sustainment |
| To inform the selection of intervention measures | Investigation |
| To inform the planning prioritisation and conduct of research | Investigation |
| To inform priorities for disease surveillance and intervention | Investigation |
| To provide information for assessing and managing risks | Investigation |
| To identify units eligible for intervention | Implementation |
| To assess if intervention measures are efficient (monitor progress, verify success) | Implementation |

Table 2. List of categories to define why surveillance is necessary (adapted from RISKSUR Terminology FAQs 3, Topic 2.1)

| REDUCE THE OCCURRENCE OF DISEASE IN ANIMAL POPULATIONS IN ORDER TO: |
|---|
| Protect the economy or facilitate trade |
| Protect animal health |
| Improve animal productivity |
| Protect public health |
| Protect animal welfare |

3.3 DEVELOPMENT OF A PRIORITISATION MODEL

A transparent and justifiable prioritisation model helps to establish a ranking of diseases and conditions for surveillance purposes. Brookes and co-workers reviewed the theory of decision-making and practices of disease prioritisation (2015). They describe the development of a prioritisation process in 4 generic steps, as outlined in Figure 4:

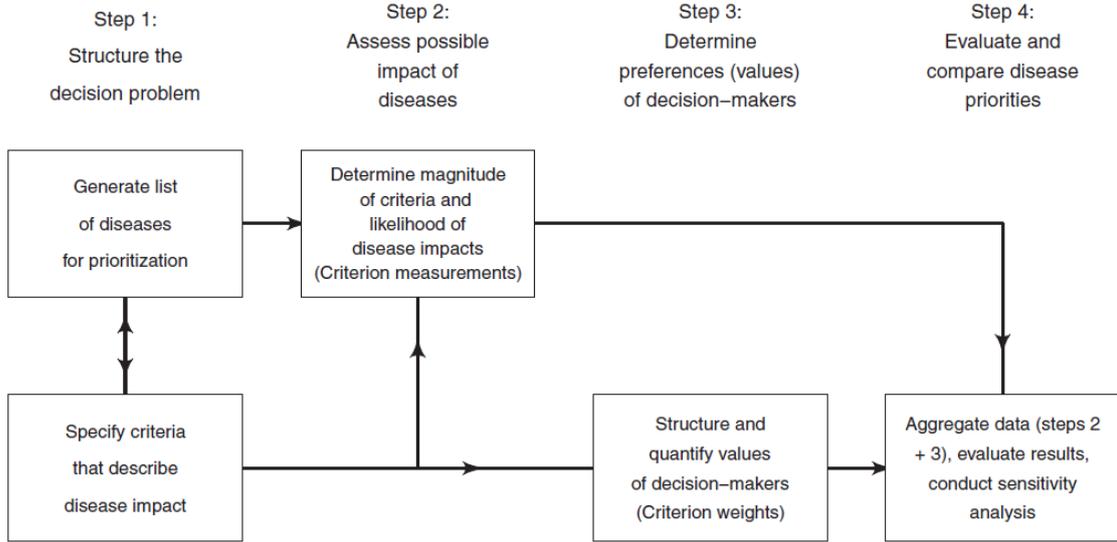


Figure 4. Schematic representation of the steps involved in developing an approach to analyse decisions regarding disease prioritisation (from Brookes et al., 2015).

Some reflections upon practical considerations in developing, implementing and maintaining such a process here below follow from the experiences that Sweden has in developing and applying such a prioritisation process (See also [Best Practice Examples 2 to 4](#)).

STEP 1 – DEFINING CRITERIA AND SCALE The source of the funding that is subject to prioritisation (1), and the surveillance mandate or responsibility that lies on that source of funding (2) can usually help define the *scope of the prioritisation process*. There may be further criteria for narrowing down the scope, for example a focus on certain species or hazards within the surveillance mandate.

Step 1 involves *specifying criteria that describe disease impact*. Examples of such criteria are given in Table 3, where they are grouped into four areas that reflect different perspectives of concerns and can be qualitative/semi-quantitative in nature (like risk of silent spread) and quantitative (like morbidity or case fatality rate).

Table 3. Example of criteria that can describe the impact of an infectious hazard

| CONCERN PERSPECTIVE | CRITERIA |
|---|---|
| Risk and epidemiology | Trend; Infectious pressure; Ability to prevent introduction; Risk of silent spread; Existence of wildlife reservoir; Prospects for control; Potential for transmission |
| Public health | Incidence; Absenteeism; Healthcare needs; Chronic sequelae; Case fatality rate; Morbidity; Preventive measures; Trend; Public concern; Preventive needs; Therapeutic needs |
| Animal health and welfare | Prevalence, Case fatality rate, Morbidity, Severity of welfare hazard, Duration of welfare hazard |
| Societal aspects incl. environmental | Economic consequences to industry; Economic consequences of control for government; Other consequences for the animal holder (e.g. stigma); Effect on trade; Effect on environment and biodiversity; Driver of antimicrobial resistance |

The *scope* and *purpose* of the prioritisation process, but also *spending as little resources as possible* and *ease of communication* will influence the relevant criteria to include and how to capture their relevance to individual hazards. The criteria ideally cover the range of stakeholders’ concerns, but should not overlap, like for instance would be the case with several criteria reflecting the same aspect. If considering zoonotic agents, the public health authorities concerned preferably define the public health criteria of importance.

Once the criteria have been decided, the *scale* by which to assess them, and the meaning of each step of that scale, has to be defined. In many instances this will be a *semi-quantitative scale*, the higher on the scale the higher the need for surveillance. In Best practice example 4 the scale for a semi-quantitative criterion in the Swedish model is -1, 0, +1.

In selecting criteria and their scale it is important to consider whether data on conditions are available so that they can actually be assessed for all hazards later in the process (see Step 2), or how they otherwise will be assessed (for example by expert opinion).

STEP 2 – HAZARD-SPECIFIC SCORING BY EXPERTS To *assess the possible impact of the hazards subject to prioritisation*, data is collected (1) and scoring of the criteria is conducted (2). This step should be *fact-based* to the extent possible, using existing data from the literature, statistics, industry and similar data. However, many times there is a lack of data, needing expert opinion to make such assessments. The work at this step in the process will therefore typically involve subject experts (on the species and hazards concerned). If several groups of experts will be involved in the assessment/scoring in Step 2 (which is likely e.g. if prioritisation involves hazards affecting many different species) consistency in scoring across hazards may be particularly challenging. It is therefore valuable to pilot test the criteria and the scoring to identify needs for clarification, before embarking on collecting data about the criteria. Irrespective of the method, the level of uncertainty

in the underlying information should be recorded. The facts should be thoroughly documented and referenced for transparency. *Each criterion will be scored*, based on the facts collected, by the same individuals that have compiled the data, or a broader group, for methodological harmonisation. Professionals involved in public health preferably score public health criteria.

STEP 3 – WEIGHTING OF CRITERION SCORES BASED ON STAKEHOLDER PREFERENCES

Whereas Steps 1 and 2 are set up to provide a fact-based background to the disease prioritisation, the purpose of step 3 is *to capture the decision makers' and other stakeholders preferences* with regard to the importance of various criteria. There are several methods to do this and the reader is referred to the literature (see Brookes 2015) for further details on these, but the general purpose is *to generate coefficients by which the fact-based scores are to be weighted*. Each stakeholder gives weights to the different criteria, which remain the same across all hazards. The weight put on the criteria is expected to differ depending on perspective of the stakeholder (e.g. government versus industry versus public, veterinary versus public health). It is therefore recommendable to involve in this exercise all perspectives concerned.

STEP 4 – COMBINING AND TRANSPARENCY These differing perspectives can subsequently *be made transparent* in Step 4, by estimating weights and reporting priorities separately for each group. It can also be used to inform sensitivity analyses. In the end a decision will have to be made on how to let difference in priorities influence the allocation of resources to surveillance; a decision which is usually in the hands of the body who holds the funding (see Step 1).

THE OUTCOME - Even with the best of prioritisation models, the outcome should never be seen as an absolute truth, but rather as an informed input to tactic and strategic decision-making. In many cases, the process itself can be just as important as the actual result, by generating good discussion and help clarifying seemingly different viewpoints.

As noted in Paragraph 3.1, priorities change over time. It may be due to changes in the disease situation itself (influencing the scoring of criteria) or by changes in the perceptions of decision makers and stakeholders (influencing the weighting). Irrespective of the source, this means that the prioritisation model has to be maintained and the process repeated with regular intervals.

2

In Sweden, a prioritisation process is being developed to inform the allocation of resources for active surveillance for infectious hazards in domestic livestock. The list of hazards as well as the assessment criteria have been defined involving actors from government, the relevant industries and farmers' organisations. The scope of the prioritisation is partly determined by a pre-prioritisation decision tree where hazards are sorted into groups with different preconditions for prioritisation; those for which surveillance is compulsory by legislation.

Thanks to parallel work at the Public Health Agency of Sweden, assessments of public health criteria for zoonotic diseases could be directly incorporated in the animal health surveillance prioritisation model. To date, weightings have not been estimated; the model ranking is based solely on the scoring of disease facts. Both the list of hazards to include (Step 1), the fact sheets and the scoring of criteria (Step 2) are subject to annual revision by species and surveillance experts.

The ranking is used to inform prioritisations both on what surveillance activities to carry out, and also on what surveillance activities should be subject to more in-depth evaluations.

The disease facts and scores, and the data synthesis and visualisation have been implemented in a spreadsheet format to allow decision makers to test "*what-if*" scenarios. As a next step, weightings will be assessed, involving representatives from both government (vet and public health) and industry.

Best Practice Example 2. The Swedish prioritisation process

3

In Sweden, the Board of Agriculture is the major source of publicly funded animal health surveillance. It is the risk managing body for animal health and welfare and thus has an interest in both exotic and endemic diseases of national concern, in all domestic animal species, including bees and farmed fish. A list of diseases for prioritisation was developed based on the national list of notifiable diseases (which in turn is based on the OIE list plus other diseases of national interest) and diseases subject to other types of national legislation. The scope of the prioritisation has set to infectious hazards in all species under its mandate, including antimicrobial resistance.

Best Practice Example 3. Step 1: The scope of prioritisation

4

STEP 1: SCALING THE CRITERIA FOR PRIORITISATION

FOR: RISK OF SILENT SPREAD, +1 MEASURED ON A 3-STEP SCALE FROM -1 TO +1.

| | |
|----|----------------------------------|
| -1 | 0 adverse conditions fulfilled |
| 0 | 1-2 adverse conditions fulfilled |
| +1 | 3-4 adverse conditions fulfilled |

“Adverse condition fulfilled” means that it applies to the hazard in the country/region.

Adverse conditions are for instance:

- Clinical signs are absent or vague
- Low awareness among animal keepers and others involved in first line detection
- Low willingness to report
- Low diagnostic capacity/unsatisfactory knowledge about the hazard

For example: if the disease is expected to give clear clinical signs, and there are good diagnostics and willingness to report, but awareness is low, this would mean only 1 adverse condition is fulfilled (low awareness). If alternatively, all this applies but the hazard would only give vague or no clinical signs, this would mean two adverse conditions are fulfilled (low awareness and vague or no clinical signs).

Best Practice Example 4. Step 1: Scaling the criteria for prioritisation

3.4 INVOLVING STAKEHOLDERS

When stakeholders are *well informed, trusting and motivated* and *understand their respective roles and responsibilities* in terms of communication and efforts, they will drive efficient surveillance. Establishing mutual trust and understanding can be based on existing networks and collaborations because of for instance other or previous surveillance activities, and/or through the inclusion of stakeholders in the entire process as early as possible, i.e. from the prioritisation process and onwards.

A stakeholder can be considered *a person or an organization with an interest in the animal health topic of interest*. This includes therefore a very broad range of perspectives from academia/research, consumers organisations, decision makers, funding bodies, international organizations (WHO, FAO, OECD, ECDC, OIE), industry/producers, non-government organizations, policy and decision makers (from the gross level to community level, including the role of the mayor), professional associations, small and medium-size enterprises, umbrella organizations (e.g. farmers, producers), veterinarians, microbiologists and laboratories as such, specimen transporters, vector control agencies, public health workers, slaughterhouses, animal handlers and transporters, animal product handlers, and many other.

A good way to be sure that all relevant stakeholders will be included is by **MAPPING** them (start by identifying them, collecting their most relevant contact information) at the beginning (of a change) of a surveillance system, i.e. from the prioritisation stage onwards. The engagement of the different stakeholders right from the beginning increases the chances that a surveillance system produces meaningful and useful outputs that will effectively benefit the overall society and thus gain general political and operational support.

Once the stakeholders are identified, holding a **FACE-TO-FACE MEETING** will facilitate the integration of their viewpoints and practicalities in the planning and design of the surveillance system. Meeting face-to-face once and if possible on a regular basis thereafter can help prevent or smoothen any possible conflicts of interest or misunderstandings. It is possible that the same stakeholders are involved in multiple surveillance components or programs related to several hazards. These meetings could therefore be organised in combination with, or back-to-back to, meetings for those other purposes or be held online via webinar or videoconferences. Discussions can be followed-up using social media channels, dedicated websites or discussion fora.

It is important that stakeholders **REMAIN ENGAGED AND INFORMED** throughout the entire cycle of surveillance. **Best practice examples 5 and 6** provide good practices how to apply participatory method for the evaluation of surveillance, and how to maintain or increase the sense of ownership of stakeholders for a surveillance system (component) respectively.

5

Using a participatory instead of a top-down approach, can enhance stakeholders' engagement. This process will enable discussion, communication, negotiation, knowledge sharing and will provide a strong basis for the common identification of socially acceptable solutions.

Participatory approaches can be defined as applied social research methods implying interactions between stakeholders, focusing on the understanding of local realities and on continuous learning. They refer to a range of methods and tools that enable stakeholders to play an active role in the definition and in the analysis of the problems they may encounter, and in their solution. By taking into consideration stakeholders' perception, needs and expectations, these approaches lead to stakeholder empowerment in the process, which may improve the sustainability of health interventions.

The complexity of surveillance systems, and the context variability in which they are implemented, entail the need for flexible evaluation tools. *Participatory evaluation* of surveillance systems (components) will provide the possibility to take into account every stakeholder's opinion. It provides a way of supporting adaptive learning, leading to a deeper understanding of the stakeholder's problem/opportunity, resources, and the broader context. The method helps every stakeholder to form judgments by describing the system, identifying evaluation criteria and giving value to these criteria. Moreover, these methods can overcome stakeholders' resistance to be evaluated. (See also example 6 (this chapter) and examples 22, 23, 24 in Chapter 7)

Best Practice Example 5. Participation of stakeholders

6

A simple method to enhance open discussion between representatives during a stakeholder face-to-face meeting is the use of a Strengths-Weaknesses-Opportunities-Threats analysis. In 1960's, Albert S. Humphrey developed the SWOT method at Stanford Research Institute (SRI)¹. It is easy to apply in a workshop or brainstorm session to review the surveillance system or component already implemented. An example coming from public health surveillance:

In January 2010, all stakeholder-representatives involved in the yearly mosquito-seasonal enhanced surveillance for dengue and chikungunya in southern France met in Paris to discuss their surveillance activities carried out in season 2009 in order to prepare for season 2010. Each stakeholder had prepared its own SWOT analysis of the system and these were discussed during a roundtable discussion. This resulted in a structured discussion that ensured the participation of each stakeholder to express experiences and concerns from their viewpoint and helped them to reach consensus to prioritise matters for improved efficiency of the surveillance system for the coming season.

¹SRI Newsletter with paper by Albert S. Humphrey: <http://www.sri.com/sites/default/files/brochures/dec-05.pdf>

Best Practice Example 6. SWOT for stakeholder engagement

3.5 TOOLBOX 3

REFERENCES

RISKSUR

Deliverable 1.1: Mapping, <http://www.fp7-risksur.eu/progress/public-deliverables>

Deliverable 7.31 (Annex): Barbara Haesler, The surveillance landscape in Europe, The Hague, The Netherlands, 30 September 2014, <http://www.fp7-risksur.eu/progress/public-deliverables>

Terminology: Frequently Asked Questions: <http://www.fp7-risksur.eu/terminology/faq>

ICAHS –2nd International Conference on Animal Health Surveillance: Main Conference Program and Conference proceedings and presentations, Havana, Cuba, 7-9 May 2014, <http://www.animalhealthsurveillance.org/index.php?n=Main.ConferenceProgram>

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4 PLANNING

4.1 SURVEILLANCE OBJECTIVES

4.1.1 Single objective surveillance

Often, surveillance is designed for a SINGLE OBJECTIVE e.g. prevalence estimation or early detection, but it can be efficient TO COMBINE SURVEILLANCE OBJECTIVES USING THE SAME DESIGN (see Section 4.1.2).

The policy purpose and the hazard (see Chapter 3 Prioritisation), its current disease status in the country or geographical area of interest, and the desired outcome of the surveillance will inform the choice of objective. Table 4 lists the four most frequently used surveillance objectives associated with livestock diseases. These are the objectives that the RISKSUR project focuses on.

Table 4. The four most frequently applied surveillance objectives associated with livestock diseases

| | | |
|------------|---------|--|
| DISEASE IS | ABSENT | Detection of incursion of exotic, new (emerging) and re-emerging diseases |
| | | Declaration of freedom from specified diseases and infections |
| | PRESENT | Monitoring of endemic diseases for disease frequency estimation: describing the level of distribution of disease |
| | | Detection of cases of disease (at the animal or group/herd level) |

Please keep in mind that *reality is never this black-and-white*. For instance surveillance to achieve *freedom from disease* is applied in the situation when a disease is assumed to be absent, but may not be, and *early detection* can be applicable to situations where the disease is present at low levels (See also the RISKSUR website for RISKSUR terminology FAQ 5 and 6 of Topic 2).

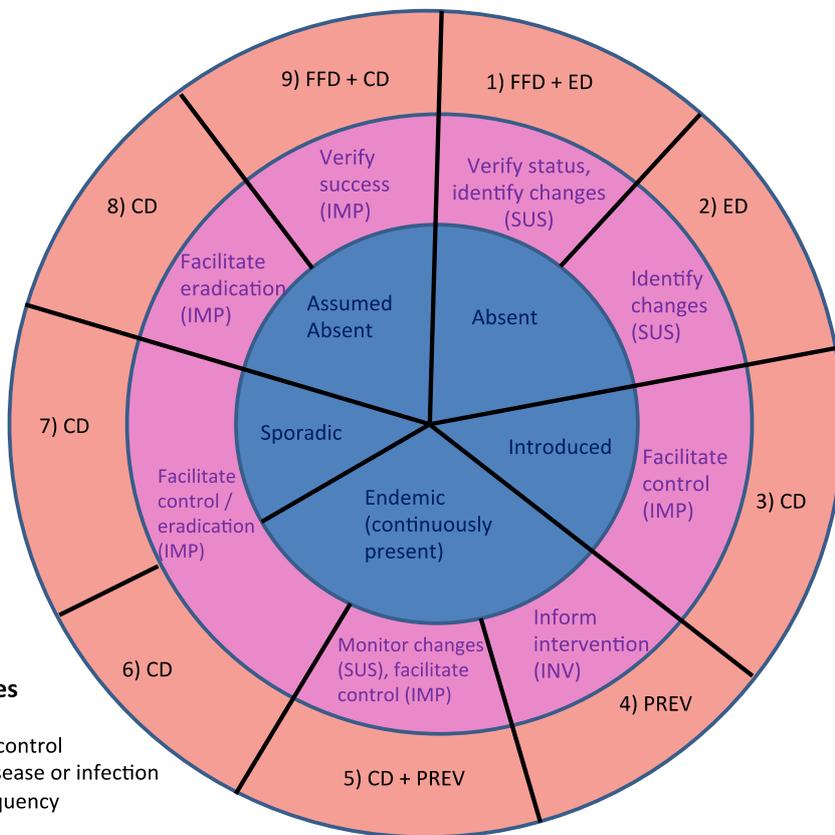
The RISKSUR surveillance design framework provides Figure 5 to aid in the determination of surveillance objective(s).

Key to diagram levels

Outer circle – surveillance objective

Middle circle – surveillance purpose (mitigation stage)

Central circle – disease status



Surveillance objective categories

- ED – Early detection
- CD – Detection of cases to facilitate control
- FFD – Demonstrate freedom from disease or infection
- PREV – Determination of disease frequency

Mitigation stage categories

SUS – Sustain; INV – Investigate; IMP - Implement

Figure 5. Diagram to help deciding on the surveillance objective (Source RISKSUR Surveillance Design Framework).

The main characteristics to fully describe the surveillance system (or its components) need to be identified (Figure 6).

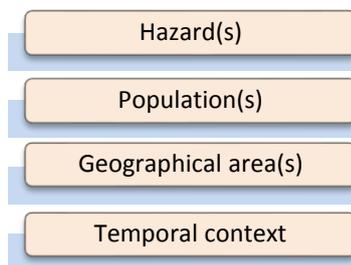


Figure 6. Characteristics to be identified for any surveillance system (component)

- **HAZARD** – In many cases the hazard is defined in the prioritisation process.
- **GEOGRAPHICAL AREA** – Many surveillance programmes are designed at national level for the entire country or a region within the country. However this depends on the distribution of disease, and the distribution, density and level of applied biosecurity of the **SUSCEPTIBLE OR**

STUDY POPULATION and the surveillance design. Targeting higher risk geographical areas would be a form of risk-based surveillance.

- **TEMPORAL CONTEXT / TIMEFRAME** – In reality and in general many surveillance activities are planned and designed on a yearly basis. Prevalence surveys may be carried out annually or less frequently while systems designed for the early detection of disease require more frequent or continuous collection of data to ensure a disease is detected in a timely manner. Also temporal or seasonal periods can apply for targeting surveillance: for instance vector borne disease surveillance for seasonal vector presence (form of risk-based surveillance).

4.1.2 Multi-objective and multi-hazard surveillance

With the objective and characteristics identified a **REVIEW OF CURRENT SURVEILLANCE SYSTEMS ALREADY IN PLACE IN THE REGION** will help identify the possibilities to avoid duplication of efforts and costs (see Figure 7). Surveillance is usually designed with a single objective e.g. prevalence estimation or early detection. But surveillance, particularly passive surveillance, is rarely designed from scratch and often a surveillance programme already in place for another hazard or surveillance objective might provide the infrastructure needed to also survey for the newly identified hazard or surveillance objective (see **Best practice example 7**). See Table 5 for the difference between multi-objective and multi-hazard (parallel and mother-child) designs.

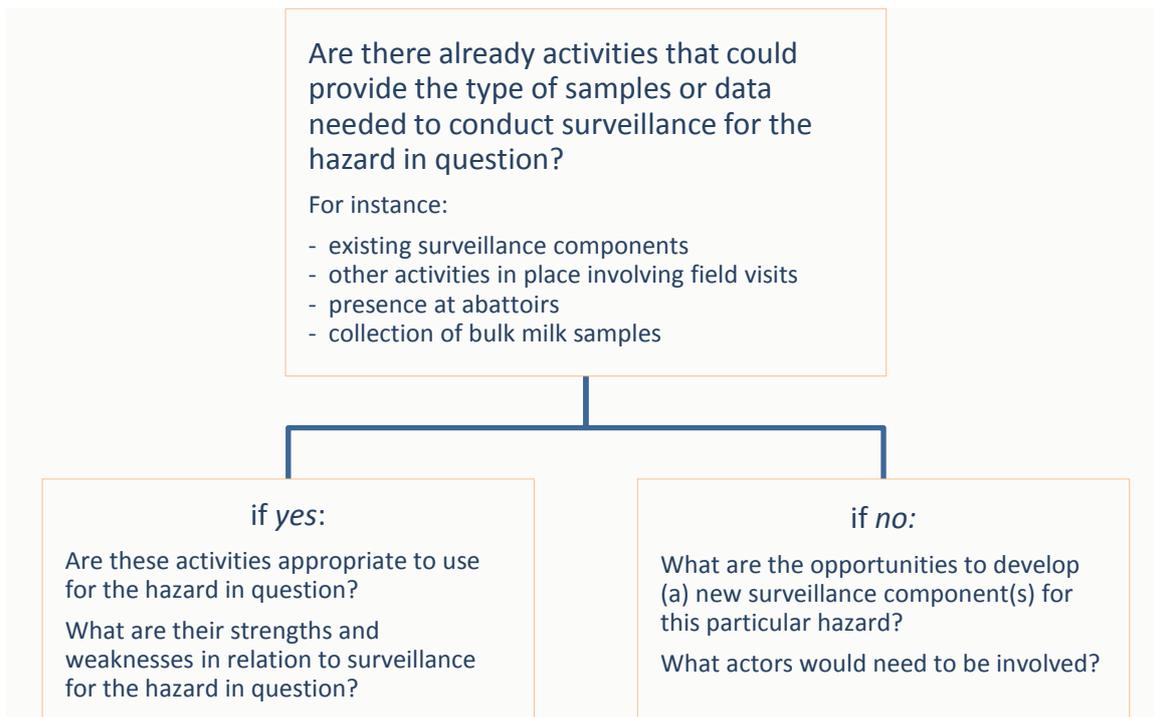


Figure 7. Flowchart of questions to consider when reviewing what infrastructure is already in place and can help reduce costs for the new surveillance objective

Table 5. Differences between multi-objective and multi-hazard surveillance designs

| MULTI OBJECTIVE | MULTI- HAZARD | |
|---|---|--|
| | PARALLEL | MOTHER-CHILD |
| <p>If surveillance activities need to serve two objectives, this needs to be considered in the design.</p> | <p>The same samples are used for the different hazards.</p> | <p>Design for a main hazard, but a subset of the samples is used to test for another.</p> |
| <p>A system may have components addressing different objectives: design components for primary surveillance objective first then design additional components where necessary to meet second objective.</p> | <p>They target the same target population and the study design, sample types etcetera are suitable to both.</p> | <p>If mother is <i>not</i> risk-based, child component can still be, if relevant data are available to select such a subset.</p> |
| <p>Note that risk-based components, will generate a non-representative sample.</p> | <p>For risk-based surveillance: identify risks for both hazards and assess whether risk-based surveillance is suitable.</p> | <p>If mother <i>is</i> risk-based, the design of a risk-based child component will be more difficult unless the risks for mother and child hazards are the same. Consider early in the planning.</p> |

7

In Sweden, surveillance schemes that are comprehensive and cover a major part of the population have been used as backbones upon which other surveillance activities have been built. One example is the national eradication scheme for bovine viral diarrhoea virus in cattle, where samples collected, during various time periods, have also been used to test for EBL, IBR, brucellosis, bluetongue and Schmallenberg virus.

Another example is the PRRS testing in pigs, which serves as a mother component to do surveillance for CSF, for Aujeszky’s disease and for atrophic rhinitis. In sheep, the national programme for maedi-visna has, in the past, been used to conduct additional surveillance for brucellosis, bluetongue, Schmallenberg and Q fever.

The existence of surveillance processes that apply efficient infrastructure is a strength of the Swedish system. The system for collection of bulk milk is highly streamlined and centralised and the same applies to collection of sera from bovines at abattoirs. With both systems, surveillance managers can target herds and animals in a very specific manner, and use existing data on risk factors to develop risk-based surveillance designs.

Best Practice Example 7. The Swedish animal health surveillance system

4.2 FROM SURVEILLANCE TO INTERVENTION MEASURES

The general purpose of all surveillance systems, regardless of their surveillance objective, is to inform or trigger timely measures once anomalies in disease patterns are detected. The implemented intervention measures are directed at disease mitigation and thus should reduce the intensity of the situation and its consequences. For this it is important that *information is reaching 'those who need to know' and 'when they need to know'* (see Chapter 6 Implementation). This requires communication *in all directions between all stakeholders involved, including policy makers and the general public*. Clearly defined communication routes, timing and responsibilities are indispensable and a worked out information system with work-protocols, including action and risk communication plans should be part of the surveillance plan mentioned in Section 4.3.

MITIGATION PROGRAMME: FROM INFORMATION TO ACTION – At any given point of time, any animal health surveillance system relates to a mitigation programme in one of three conceptually distinct ways. Each stage differs in terms of the objectives of surveillance, the potential for avoided losses and the costs incurred (Haesler et al., 2011). The stages are: *Sustainment*, *Investigation*, and *Implementation* (see Figure 8). The stage of a system has implications for the type of actions triggered by surveillance-findings.

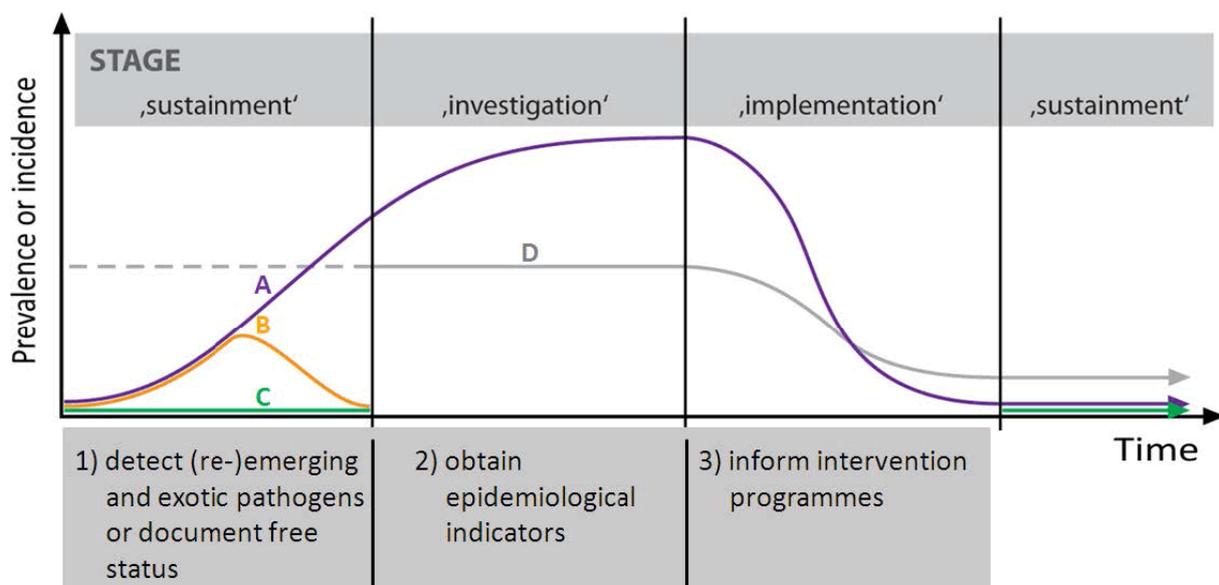


Figure 8. Mitigation programme: 3 conceptually distinct stages and how surveillance relates to them. A: (re-)emerging or exotic epidemic pathogen that is not controlled by response measures; B: (re-)emerging or exotic epidemic pathogen that is controlled by response measures; C: continuous free status; D: endemic disease where the dotted line means that the true value is unknown. (From Haesler et al., 2011)

Sustainment:

- Sustainment is to protect a free or acceptable disease status, by taking steps to prevent an infectious agent/disease becoming established in an animal population.
- Surveillance is conducted to document that the threat remains absent or low, and to give early warning of an increase in disease cases: expenditures are made in the expectation that surveillance now enables losses to be avoided in the future, thus minimising the need for subsequent mitigation expenditures.

Investigation:

- Investigation is needed if the disease situation is not fully understood or not under control.

- Surveillance is to provide critical technical information about disease occurrence, its transmission pathways, and other considerations leading to the design of appropriate intervention strategies to reduce or eradicate the disease. This should also include estimating the implications of the technical options for financial costs.
- When used to inform the implementation of a mitigation plan, investigation can be viewed as a fixed cost necessarily incurred for implementation to take place.

Implementation:

- A mitigation activity is being implemented.
- Surveillance is to inform the choice, timing, and scale of intervention, and documents the progress of intervention directed at disease reduction.
- Following successful implementation the mitigation objective may revert to sustainment of a free or acceptable disease status, however the technical characteristics might have changed.

INTERVENTION MEASURES can be actions ranging from treatment, quarantine, transport bans, sanitary rings, vaccination plans, culling, biosecurity measures, create disease awareness and more.

RISK COMMUNICATION is an interactive process of the exchange of information and opinion among individuals, groups, and institutions. It involves messages about the nature of the risk and how the risk is perceived through expression of opinions and concerns. Risk communication should be adapted to the audience, in terms of use of language for instance, for the intended message to come across (see **Best Practice Example 8**). The Centers of Disease prevention and control (CDC) provide a list of what topics should be included in a risk communication plan.

8

RISK COMMUNICATION TODAY¹

It is the *perception by the receiver* of the message that determines what and how it is understood. The language used is of key importance. Depending on the audience the use of jargon and scientific terminology should sometimes be avoided. A message is better received if the communicator expresses an understanding of the concern that the receiver has regarding the topic. The receiver will be more receptive if they feel heard and understood. If the receiver thinks that action can be taken to reduce (the effects of) the risk, the receiver is more open to the communicated message. The perception of the message is influenced more by the feeling the receiver has than by facts. An example of what the effect can be of using scientific terminology and how it can increase fear: when communicating that *hydrogen dioxide* was used for animals and weeds, many people perceived this as a higher threat than the use of *pesticides*. If they had used the term *water* instead, this perception would probably have been the inverse.

See also:

Risk communication today - presented by Olivier Espeisse (International Federation for Animal Health Europe (IFAH), Brussels, Belgium <http://www.ifaheurope.org>) (adapted from Professor Anton Oppenhuizen and Carla Geijskens, Office of Risk Assessment and Research Netherlands Food and Consumer Product Safety Authority and Maastricht University, Department of Toxicology, New approaches on risk communication: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part2_PPT_Antoon_OPPERHUIZEN.pdf , for World Trade Organization Thematic Sanitary and phyto-sanitary measures Workshop on Risk Analysis, Geneva, 13-14 October 2014 https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/wkshop_oct14_e.htm and Summary: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part2_Summary_Anton_OPPERHUIZEN.pdf)

A fresh look at how to approach risk communication - presented by Matthew Perkins (senior marketing manager for Global Consumer Insights Elanco Animal Health)- https://eufmd.rvc.ac.uk/pluginfile.php/5013/mod_page/content/8/Risk%20communication%20webinar%20June%202015.pptx

¹ From the EU-FMD webinar on risk communications, held and recorded on 3 June 2015 <https://eufmd.rvc.ac.uk/mod/page/view.php?id=2461>

Best Practice Example 8. Risk communication today

4.3 DOCUMENTATION, WORKING PROTOCOLS AND TEMPLATES

It is good practice to document as much as possible the following details during the planning and subsequent design phase: drivers and decisions, case-definitions, stakeholders and their respective responsibilities, activities, communication flows, action flows, timelines. This can provide the surveillance document/protocol, ultimately reaching the OIE-recommended level of a **SURVEILLANCE PLAN** (Figure 9).

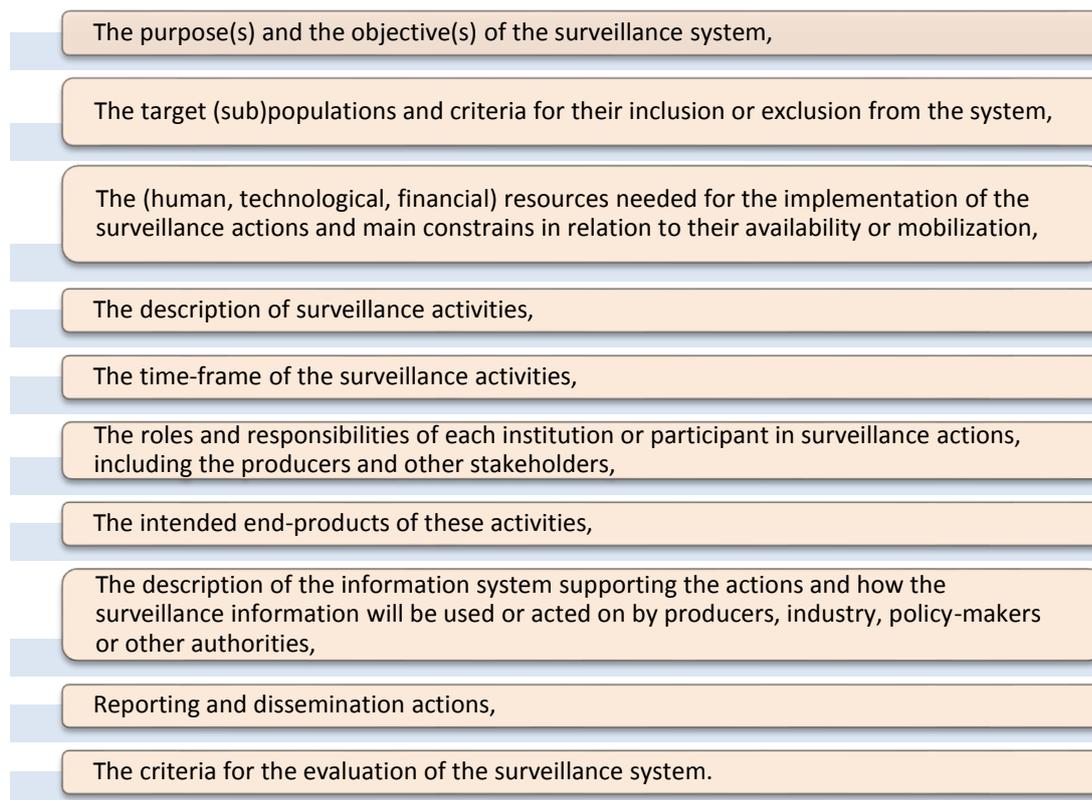


Figure 9. List of surveillance related aspects to work out in detailed working plans and templates

Ideally, the content of the plan should be coherent and worked out clearly enough to be understandable to the less-technically-skilled.

The (re-)planning and (re-)designing of a surveillance system (component) should include a plan for evaluation and monitoring activities to ensure that the system remains flexible to change. It needs to be adaptable to changes linked to one or more of its drivers, e.g. epidemiological, biological, ecological, economic, social, cultural, political and environmental factors. Evaluation provides advocacy elements, for changes of the system *ad hoc* (fine-tuning) or to a larger extend for (re-)planning and (re-)design or to end the activities (exit), and success stories to inform good practices (See Chapter 7).

The plan is usually completed and annexed by a series of *standard operating procedures* (work protocols) and *templates* giving detailed instructions on whom, how and when to do the activities. This provides guidance and improves a standardised way of working and will for instance provide case definitions, instruct on how to collect samples and dispatch them to which laboratory, how to fill forms and where and when to send them to or how to enter information in an automated information systems. (Secured) online availability of surveillance plans, will ensure accessibility of the latest updated version, and provide access through direct links or consultable documents to templates, contact and address lists, and specific parts of the plan.

4.4 TOOLBOX 4

REFERENCES

CDC Healthcommunication - <http://www.cdc.gov/healthcommunication/risks/index.html>

OIE guide - <http://www.oie.int>

RISKSUR Terminology FAQs – <http://www.fp7-risksur.eu/terminology/faq>

Haesler, B., Howe, K.S., Staerk K.D.C., 2011, Conceptualising the technical relationship of animal disease surveillance to intervention and mitigation as a basis for economic analysis, *Biomed Central Health Services Research*, 11;225 <http://www.biomedcentral.com/1472-6963/11/225>

5 RISK-BASED DESIGN

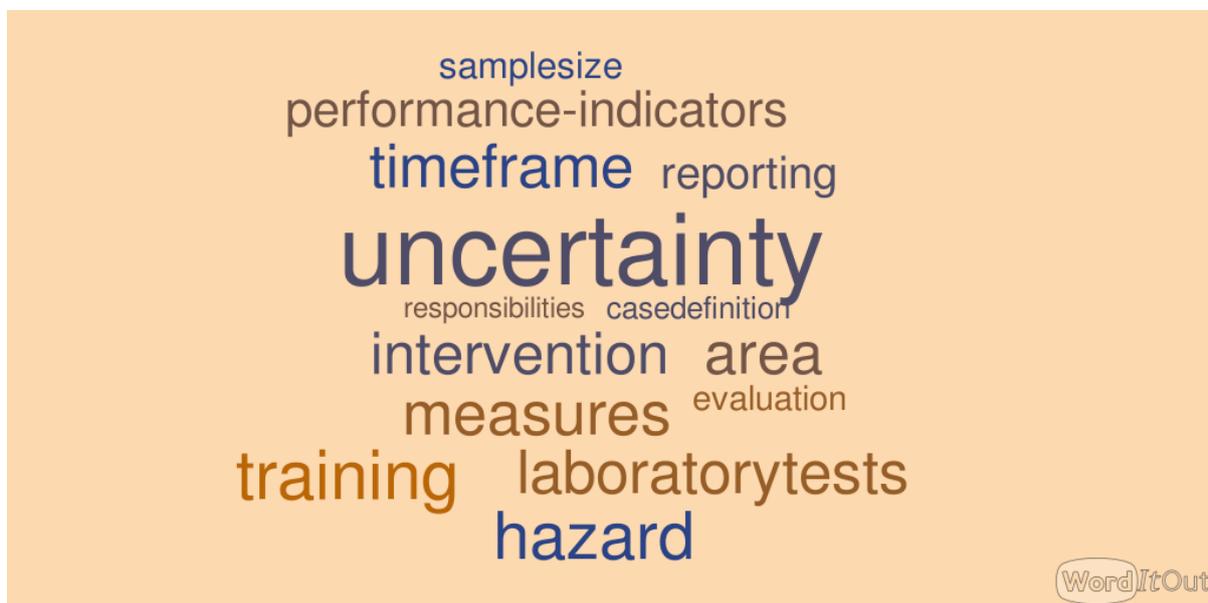
5.1 GENERAL CONSIDERATIONS

To design an effective surveillance system two things are needed:

- An understanding of available surveillance design options (this chapter), and
- An ability to compare and evaluate the different options, so that the best combination can be selected (see this chapter and Chapter 7).

This chapter reflects upon good practices and insights in different designs for surveillance system(s) (components) for each of the four surveillance objectives (See Section 5.2). It therewith supports informed decision making between risk-based or other types of surveillance design (active, based on random sampling, or passive) as the preferred option. While designing the surveillance system or its component(s), documentation of all decision-steps and working protocols will result in the aforementioned detailed surveillance plan (see Section 4.3). A tool helping a team going through all the steps, and to document all choices made during the design, is the RISKSUR Surveillance Design Framework (see Toolbox 5).

Although it is impossible to cater for every factor and situation, information in this chapter and references to the surveillance design framework will provide the instruments to take informed decisions.



5.1.1 Case definitions

The first step in taking actions against a disease is to identify the cases, meaning the individual or epidemiological units having the defined characteristics of the disease under investigation. Case definitions should be *clearly and simply formulated*, being clear on specific details on individual or herd-level, about animal species, age group, geographical region, time window, clinical signs, and/or

possible previous exposure to other epidemiological units within time window. Different case definitions can be made for suspected or probable and confirmed cases. The level of detail of a case definition is closely linked to the purpose and objectives of surveillance or mitigation activities, whether it matters to what extent cases can be missed by the system or not, and therewith has consequences on the amount of resources for surveillance and mitigation activities to be invested.

5.1.2 Surveillance components

Depending on the objective, the surveillance system will comprise one or more surveillance components, each focusing on a different target population or using a different study design but all with the common objective and hazard described above. Besides designing a surveillance system (component) for one surveillance objective or for one surveillance hazard only, the opportunities to design for multi-objective and multi-hazard surveillance could be present and would help reducing needs for resources (see Chapter 4. Planning).

The design of the specific surveillance components that will make up the surveillance system started with the exploration and definition of its *main characteristics*, i.e. hazard, population, geographical area, temporal context/timeframe (see also Chapter 4). The decision for a risk-based approach may only be reached after having assessed the *factors that may divide the population* into higher and lower risk sub-populations and *the availability of data* to allow for identifying these strata.

5.1.3 Risk factors

Risk factors are any factors that influence the distribution and/or the consequences of the hazard in the population of interest. Such factors may be present at the population level, at the herd level or at the individual level, and can be used to improve the cost-effectiveness of surveillance by allocating relatively more surveillance efforts to population strata at higher risk. In Chapter 2, risk factors and how to identify and assess them is briefly introduced.

Examples of risk factors at different levels are:

| INDIVIDUAL | HERD | POPULATION |
|------------|-------------------|--------------------|
| Sex | Herd size | Seasonality |
| Age | Animal movements | Geographical niche |
| Breed | Production system | |

Once the factors are identified, more insight into to what extent they play a role may come from previous investigations in the population in question, or from the literature. Information on stratum-specific prevalence, or relative risks between different population strata will be important for further design. And even more specifically, whether data on the factors of interest are available for the units in the population that the surveillance will target (e.g. herds).

5.1.4 Risk-based surveillance

In risk-based surveillance, the system or its component is designed so that *efforts are targeted (more) at the identified high-risk groups*. The strategy to target subpopulations at higher risk is based on the observation that the probability of occurrence of a certain disease or infection is not the same, i.e. not randomly distributed, across the entire population, but some individuals (subpopulations) have a *higher probability of contracting or showing the infection*. Risk-based surveillance can also be targeted at subpopulations where the *consequences are higher*, should disease be introduced. The focus is then primarily on units that are highly connected and where any introduction of disease would spread rapidly through the population. Examples would be production systems with a high level of biosecurity where units are highly connected, e.g. swineherds at the top of the breeding pyramid, grandparent poultry flocks. Risk-based surveillance is an option for all the surveillance objectives, but careful consideration is needed on how it is implemented (See Section 5.2).

5.1.5 Disadvantage of risk-based surveillance

As this section illustrates, risk-based surveillance requires prior epidemiological information and epidemiological skills in order to design and evaluate surveillance. Equally, making inference from the results to the entire population is more difficult. Because of this, the comparison with other surveillance designs, e.g. between trading partners (equivalence), is more challenging. Therefore it is important that both, *epidemiological expertise in the team* and *the data needed to design and analyse the system*, are available.

It is important to keep transparent documentation on decisions made and methods used to allow assessing the accuracy and degree of uncertainty of any assumptions and input parameters used as part of the design. If applied, this will form the basis for enhanced transparency and standardised ways of documenting surveillance.

The following sections address more in detail, for each of the four surveillance objectives, if risk-based surveillance is or can be a good option, providing good practice examples.

5.2 DESIGN CONSIDERATIONS BY SURVEILLANCE OBJECTIVE

5.2.1 *Absent diseases* - Early detection of the incursion of new, (re)-emerging or exotic diseases

The main objective for the early detection of diseases that are (re)-emerging or new and/or exotic to a population is to increase the possibility for the mitigation of the disease and its effects through rapid response (see Section 4.2). The interest to detect and mitigate diseases is often higher if the consequences for the affected population are expected to be high, e.g. high reproductive number/very contagious, severe public or animal health consequences, or having an associated high economic impact. Early detection can also be desired for diseases that require more complicated control measure for instance because of the involvement of wild animal or vector reservoirs.

5.2.1.1 Pathogen detection versus (clinical) disease detection

Usually pathogen replication precedes the manifestation of clinical signs. It would be preferable to detect the pathogen in the population before clinical signs appear. However, this is not always possible. Besides that it is not known what to look for and diagnostic tests might not be readily

available, e.g. new diseases, a test might be available but not sufficiently sensitive to pick-up cases, e.g. tuberculin test for bovine tuberculosis screening, the causative agent might be found in tissues accessible only at post-mortem, e.g. prions in mad cow disease or bovine spongiform encephalopathy (BSE), or the evolution of the disease has a chronic nature and the earliest we can detect the infection is by testing the hosts' immune response, e.g. IFN test for tuberculosis. Therefore, the detection of the pathogen before clinical manifestation might not always be possible.

However, the detection of the disease instead of the pathogen in animals could be early enough to prevent spread of the pathogen to another animal species or human population, e.g. West Nile virus, rabies or BSE. If disease occurs both in domestic and wildlife populations, it is depending on the pathogen in which population early detection is more feasible, e.g. avian influenza, African swine fever, West Nile virus. Likewise, vector borne diseases are often detected in the animal instead of the vector population.

The most common approach to detecting incursions of known diseases is case reporting. Most countries have a legal basis that make the notification of cases compulsory and also provides case definitions and specifies the diagnostic tests to be used.

5.2.1.2 Surveillance design

Risk-based surveillance

To detect a newly introduced infection or disease in a population with a certain level of confidence (see Section 5.2.2 and 5.2.3), ideally the entire population should be under surveillance. But when diseases are unknown or very rare to the population, the people having to signal or report suspicions are likely to miss them. Active surveillance could focus on populations at expected higher risk, through estimated probability of introduction, if those populations are known.

As seen in Chapter 2, risk can be defined as the likelihood of the occurrence (probability) and the magnitude of the adverse effects (consequences) to animal or human health, given a specific series of events (scenario) occurring in a specified time period. Hence risk can be defined as the probability of incursion of an infection or disease in a susceptible population and its consequences. The *relative risk ratio* will measure how much greater the probability of getting infected in the high-risk stratum is compared to the low risk stratum (See Section 5.2.2).

The probability of introduction and the magnitude of its consequences are closely linked to factors like:

- The prevalence of the disease of infection in epidemiologically linked areas or populations;
- The presence of susceptible animals;
- The transmission pathways;
- The epidemiological conditions that favour infection through each of the identified transmission pathways.

By definition, uncertainty is a big challenge when to survey for early detection of new or (re-)emerging diseases. The probability of introduction and exposure of infection can differ for different populations and be unknown or uncertain. This is particularly the case for multiple-host and vector-borne infections, where the role played by each species might not be elucidated and where the knowledge on different vector species, vector ecology, and infection dynamics in vectors or even on vector distribution might be scarce.

When risk-populations are distinguishable (which may not be the case for previously (completely) unknown diseases), risk-based sampling might be suited for (re-)emerging diseases. This might also

generate knowledge to feed risk assessments through refining parameters. Risk assessment can be used to identify regions, farms, industries or animals that are most likely to be exposed to a novel agent. If sufficient knowledge is available, such factors can be used to focus surveillance efforts. An efficient risk-based strategy for early detection of an exotic or (re-)emerging disease may be to focus surveillance efforts on herds or flocks that import animals. Or, by focusing surveillance in the species from where spillover to another species is expected: for instance the surveillance for West-Nile virus is focusing on wild birds and horses, to be able to prevent human cases.

Syndrome surveillance

New infections could be detected when a system is in place to register *syndromes* and *anomalies from expected patterns*. This was for instance how Schmallenberg virus (SBV) was discovered in Europe. SBV caused few clinical signs in adult animals, with no indication of the possible source and little evidence about its spread or means of transmission. The systems in place in Germany and the Netherlands detected disease initially. Data from the automated cattle milking systems and farmer-derived data on reporting non-specific clinical signs gave the first indications of a widespread issue. Microarray technology was used to identify SBV as a new pathogen (Roberts et al., 2014).

For some infectious diseases, the *detection of fever or changes in behaviour* can indicate the onset of infection. In such cases, “early detection” is directed at the observation of a change in pattern in what is considered “normal” behaviour in situations without infection. This is currently (experimentally) being tested for infections in pigs under the EU funded project Rapidia (<http://rapidia.eu>). The method focuses in particular on African swine fever (ASF) and is based on ruling out ASF via different steps, using biosensors for 24 hours a day monitoring behaviour and activity. The information from the sensors can be retrieved, processed and analysed remotely and in real-time. A possibility is to apply this method for *sentinel areas/animals at higher risk of exposure*.

Similarly, *non-specific indicators from data analysis*, e.g. changes in trends or clustering of drug sales, or non-confirmed lab results, could suggest unknown or undetected diseases. This approach for early detection of (temporarily) absent diseases is becoming a part of surveillance systems in several countries. In the national animal health surveillance programs in Sweden and the Netherlands syndromic surveillance is applied based on laboratory results. See the website of the European project Triple S, syndromic surveillance in Europe, for an overview of syndromic surveillance in animal and public health surveillance.

5.2.1.3 Summary

SURVEILLANCE TO DETECT NEW OR (RE-)EMERGING DISEASES EARLY:

- Early detection refers to detection of infection or clinical disease as early as possible to be able to implement mitigation measures to avoid further losses because of spread of the disease;
- Could be carried out *continuously or periodically*, with increased frequency when the risk of introduction is higher and related consequences are expected to be of interest;
- Can be risk-based when populations at higher risk of introduction and exposure are known and/or when consequences of introduction are expected to be high, for instance when the infection is known to cause irreversible damage; for which there are no treatments or vaccines available or permitted; for those that are vector-borne or for those that circulate in a wildlife reservoir before affecting end-host species (livestock or humans);
- Could be *based on the analysis of data of syndromes* (syndromic surveillance).

9

A surveillance programme to detect Rift Valley fever (RVF) in ruminants is set up in Country X with favourable climatic conditions for and presence of several competent RVF transmitting mosquito species. Wind is known to be able to transport these mosquitoes (vectors) over longer distances than they could travel by flying. The country never detected RVF before and until now only passive surveillance of clinical signs was applied. In neighbouring countries RVF is known to be present intermittently, albeit likely underreported due to the fact that surveillance is passive and relies on reporting and that the infection often remains subclinical.

A few times a year, coinciding with favourable climatic conditions leading to abundant competent mosquito populations, live ruminants are being moved and home-slaughtered for social festivals between Country X and neighbouring countries. These movements of animals are not under veterinary control, i.e. illegal.

All these factors could lead to ruminants and the vector population in Country X to become infected with RVF. When taking them into account, a way to early detect RVF incursion, is to focus efforts at the probability of introduction and hence at the possible origins of infection:

A possibility could be to target the geographical areas at the border that have a presence of susceptible species, both domestic and wild ruminants, through:

- A. A *monthly survey from representative sample of those ruminants*, in the months when vector abundance is highest, for instance between May and September. An issue could be to calculate an appropriate sample size. This could require considerable resources and logistics, for instance when the expected prevalence is 5%, the sample size will be large.
- B. A *sentinel surveillance system* directed only at those areas or populations assessed to be at higher risk, because of known previous outbreaks across the border, higher ruminant density, more suitable conditions of higher vector abundance, wind directions, etcetera. The resources and logistics required could be less than for possibility A.

Best Practice Example 9. Detection of Rift Valley fever in ruminants in suitable vector climate

5.2.2 Absent diseases - Demonstrating freedom from disease (or pathogens)

Demonstrating freedom from disease is a common requirement for a country, region or individual herd to be able to participate in the **TRADE** of animals and animal products or to avoid having to provide additional guarantees (e.g. pre-movement testing). Besides, disease freedom may also offer important **NON-TRADE BENEFITS** such as improvement of public health, decision-support when to finish an eradication programme and elimination of losses and intervention costs due to endemic disease.

See [Annex A](#) for [Best practice examples 10, 11, 12, and 13](#).

Best Practice Example 10. Risk-based sampling

Best Practice Example 11. Combination of evidence from multiple components

Best Practice Example 12. Risk-based requirement to calculate sample size

Best Practice Example 13. Risk-based requirement to calculate probability of freedom

5.2.2.1 Challenge of demonstrating disease freedom

The challenge of demonstrating disease freedom is that it aims to provide *evidence that the respective disease is absent*. Hence, surveillance is *designed to detect the disease if it is present even though at a very low level*. Since diagnostic tests are generally imperfect (OIE, 2014: Validation guidelines. 3.6.5 Statistical approaches to validation) thus resulting in false positive and false negative test results, *absence of disease can often not be proven with absolute certainty*. In some scenarios, the required level of evidence cannot be obtained at all. Instead, the aim is to provide sufficient evidence to show that, if a particular pathogen is present, it is *present in less than a specified proportion of the population (design prevalence, P^*) at a given level of statistical confidence*.

Hence, rather than aiming to document absolute freedom, the objective is *to estimate the “probability of freedom from disease”* and its opposite, *the “probability of disease”, given that all test results are negative*. Applying this probabilistic approach *allows considering accumulative evidence*, such as taking results from different surveillance activities (structured and non-structured) and data from previous surveys into account.

5.2.2.2 Combination of surveillance components aimed at demonstrating freedom from disease and early detection

A surveillance system with the objective to demonstrate freedom from disease generally includes at least one surveillance component aimed at early detection. To understand this relationship, two likelihoods need to be distinguished when designing surveillance aimed at demonstrating freedom from disease:

- The likelihood that the hazard is still present in the population = *risk of (residual) infection*,
- The likelihood that the hazard will be re-introduced = *risk of (new) introduction*.

Surveillance with the objective of demonstrating freedom from disease is generally based on *ad hoc surveys* designed to detect disease in case the population is infected at or above the specified design prevalence, thus targeting the **RISK OF RESIDUAL INFECTION**. In contrast, early detection aims to detect new introductions early and involves *continuous surveillance or surveys in short intervals*. Hence, the early detection component provides additional evidence that **NO NEW INTRODUCTIONS** have occurred since the last survey. This is particularly important *to estimate the prior probability of freedom* when taking historical data into account.

AS A GENERAL RULE, the hazard situation influences the emphasis placed on *ad hoc* surveys:

| | |
|--------------|--|
| POST ENDEMIC | After elimination of an endemic disease or an outbreak, the likelihood of residual infection is still relatively high. Therefore, surveillance with the objective of <i>demonstrating freedom from disease</i> is important to be included. |
| FREE | If disease has never been present or has been absent for a long time, then the risk of residual infection becomes negligible so that activities focus more strongly on the risk of introduction and thus <i>early detection</i> . |

5.2.2.3 SURVEILLANCE APPROACHES

Surveillance to demonstrate freedom from disease is particularly suitable to apply output-based standards or risk-based approaches as the aim is not to provide representative estimates, but to detect disease in case the population is infected at or above the specified design prevalence. The following sections provide information on non-traditional surveillance approaches relating to:

- A. Application of risk-based sampling;
- B. Combination of evidence from multiple components to estimate performance of the entire surveillance system;
- C. Application of risk-based requirement.

A combination of these approaches is also possible (Welby et al. 2012, Frössling et al. 2013).

The reader is referred to reviews and general guidelines for further details (Stärk et al. 2006, Cameron 2012, European Food Safety Authority 2012, Reist et al. 2012, Oidtmann et al. 2013, Cameron et al. 2014).

A. RISK-BASED SAMPLING

Risk-based sampling has been defined as a surveillance design preferentially sampling those strata (sub-groups) within the target population that are more likely to be exposed, affected, detected, become affected, transmit infection, or cause other consequences (Hoinville et al. 2013). *For disease freedom*, Cameron (2012) suggested that the risk of consequences is not of primary importance as the aim is restricted to demonstrating the absence of disease. On the contrary *for early detection* both, likelihood of infection and consequences, are important aspects to consider.

By looking for disease in animals or population strata that are more likely to be infected or detected, *the probability of finding disease increases*. Hence, *risk-based sampling is particularly useful to demonstrate disease freedom* since disease is expected to be absent or, if present then at very low levels. By assigning a higher probability of selection to units from high-risk strata compared to those from low-risk strata (*stratified sampling*) or selecting animals from high risk groups only (*targeted sampling*) (Figure 10), the likelihood of detection is expected to increase. If likelihood of detection increases, risk-based sampling may achieve the following when compared to conventional approaches:

- Increased surveillance sensitivity at the same sample size (see [Annex A](#) for *Best practice example 10*) or,
- Reduced costs through a reduction of sample size at constant target sensitivity.

In multi-stage sampling designs, selection of units from within a stratum should generally be performed at random to achieve representativeness.

See also: Alban et al. (2008), Hadorn et al. (2009), Schuppers et al. (2010), Welby et al. (2012).

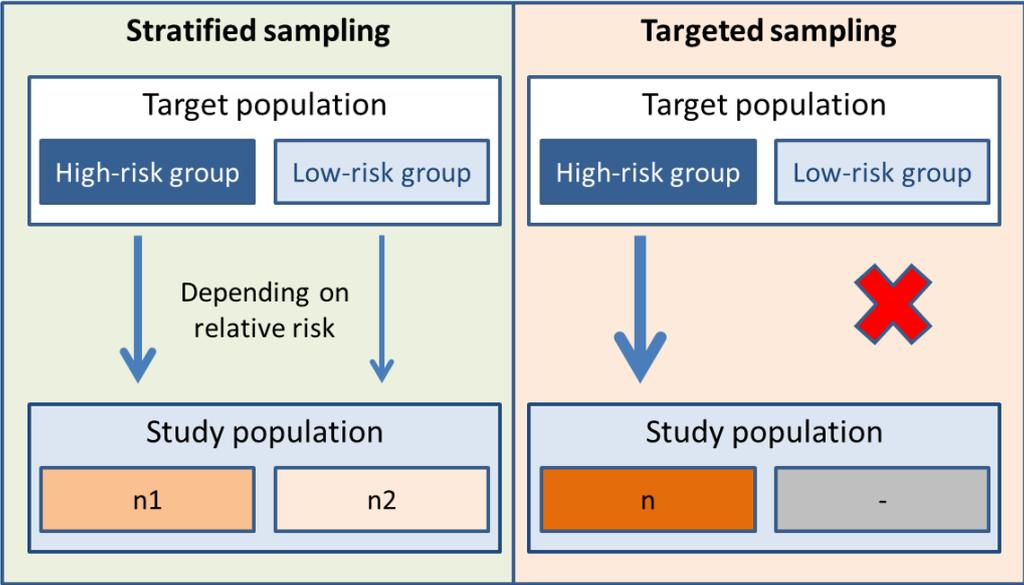
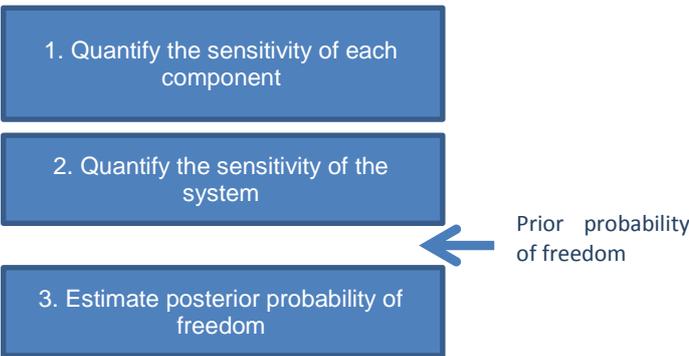


Figure 10. Risk-based sampling distinguishes between high- and low-risk strata of the population. Subsequently, two approaches may be chosen: A) Stratified sampling: all animals have a nonzero probability of being selected but sampling intensity varies between risk-groups resulting in two sample sizes (n1 and n2); or B) Targeted sampling: sampling is concentrated on a defined sub-population that is expected to have a higher prevalence of the disease which results in a single sample size (n).

B. COMBINATION OF EVIDENCE FROM MULTIPLE COMPONENTS

By applying a probabilistic approach, it is possible to analyse data from complex surveillance systems that include data from *structured* (e.g. surveys) and *non-structured sources* (e.g. passive surveillance, meat inspection, necropsy).

The steps to combine evidence from multiple components are illustrated in Figure 11. The sensitivity of each individual surveillance components (CSe) is estimated as each of them provides additional evidence that disease is not present if no positives are found (1).



Subsequently the components sensitivities are combined to obtain an overall estimate of the performance of the entire surveillance system (SSe) (2). Finally, the probability of freedom (PFree) can be calculated based on the sensitivity of the surveillance system and an estimate of prior probability of freedom (3)

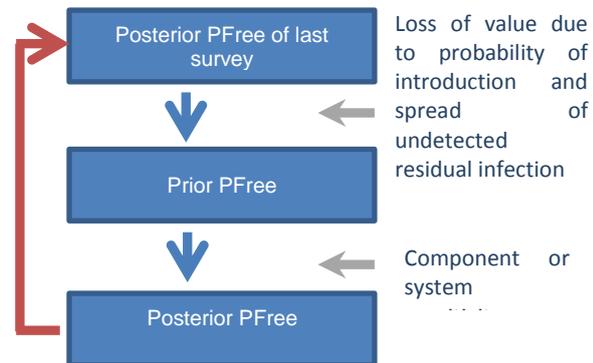
Figure 11. Steps involved in combining evidence from multiple components to calculate probability of freedom

For more information see also: Martin et al. (2007b), Wahlström et al. (2010), Christensen et al. (2011), Welby et al. (2012).

C. RISK-BASED REQUIREMENT

Risk-based requirement assumes that the confidence of a population to be free from disease accumulates over time and does not drop to zero between subsequent surveys. Two parameters are needed to calculate PostPFree (Figure 12):

- PriorPFree
- Cse or SSe achieved since the last survey.



PriorPFree is estimated based on PostPFree of the last survey and the estimated loss of value of this information since the last survey. Loss

of value of historical data depends on the probability of introduction and the probability of spread of undetected residual infection (Knopf et al. 2007, Schwermer et al. 2009).

Figure 12. Stepwise analysis of historical data. PFree: Probability of freedom

This method can be used to calculate sample size to achieve a target probability of freedom (see [Annex A](#) for [Best practice example 12](#)) or to obtain an accumulated measure of probability of freedom over time (see [Annex A](#) for [Best practice example 13](#)).

For more information see also: Hadorn et al. (2002), Knopf et al. (2007), Alban et al. (2008), Schwermer et al. (2009), Schuppers et al. (2010), Welby et al. (2012).

5.2.2.4 Summary

SURVEILLANCE TO DEMONSTRATE FREEDOM FROM DISEASE:

- Generally includes components *aimed at early detection* in order to address the risk of new introductions;
- Allows analysing data from *multiple* (structured and un-structured) *sources*;
- Can benefit from risk-based approaches, as these increase the likelihood of detection (risk-based sampling);
- Allows incorporating historical information to reduce the sample size required to achieve the target performance (risk-based requirement).

5.2.3 Present diseases - Describing the level of disease occurrence

Epidemiological measures to describe disease occurrence are *prevalence* and *incidence* (see Textbox 2). Knowing the level of disease occurrence is important for 1) priority setting (e.g. decide whether to institute a programme to either control or eradicate the disease) and 2) to provide data for risk analysis. It can also 3) serve as proxy to estimate disease impact in economic analyses.

Textbox 2

Prevalence is the proportion of (disease) cases in the population at a given time. It conveys information on how widespread the disease is.

Incidence is the rate of new (newly detected/identified/diagnosed) cases of disease. It is generally reported as the number of new cases occurring within a period of time (e.g. per month, per year). It conveys information about the risk of contracting the disease.

5.2.3.1 To detect changes

More often, estimates of prevalence or incidence are used *for comparison*, in order to detect changes in the level of disease over time, between geographical areas, or in relation to other risk factors. For example, comparing the level of disease over time can be used to detect changes in the disease distribution that in its turn might trigger a mitigation programme. It can also be used to assess the effectiveness of an existing disease control programme, by verifying if the disease prevalence is decreasing. Comparing the level of disease between two geographical areas can be used for instance to plan the establishment of a disease free zone. In this case, first areas at low prevalence need to be identified, that then will be subjected to stricter disease eradication efforts in order to eliminate the last cases of disease, towards becoming a disease-free zone.

5.2.3.2 For decision-making

When measures of prevalence or incidence are required for decision-making, surveillance must ensure reliable estimates of such epidemiological parameters. The key aspect to ensure reliable measures of disease frequency is to adopt a representative sampling strategy, meaning the data generated must come from *a sample representative of the population*. Therefore, *risk-based sampling* approaches are *not suitable for this purpose*, as they intentionally generate selection bias towards the high-risk groups: risk-based sampling allocates relatively more investigations to population strata where disease is more likely to be present and/or detected, being therefore non-representative of the general population (See **Best practice example 14**). It therefore yields disease estimates that are intentionally biased. If the extent of bias was known, the level of occurrence in the reference population might be estimated.

14

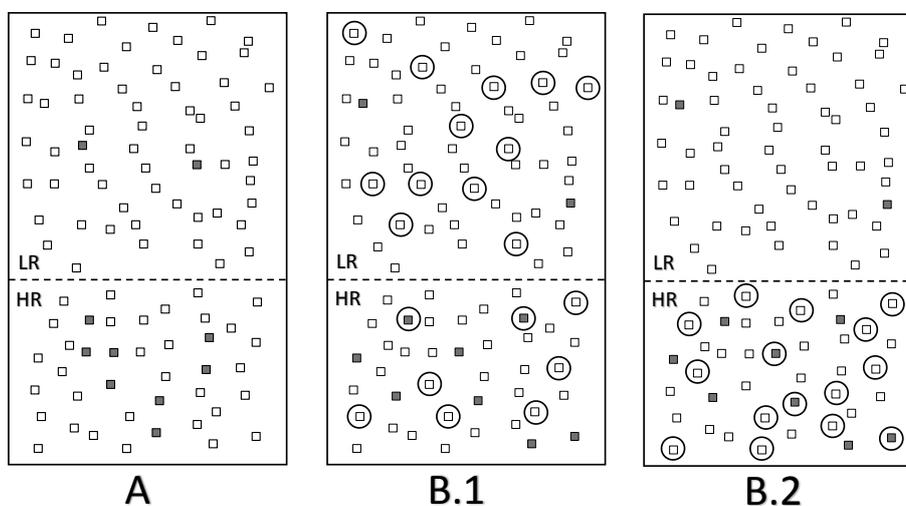
A surveillance program to monitor the level of Aujeszky's disease in wild boars is in place in a given country. The goal is to detect any change in the level of disease that might trigger a control program. The baseline disease level (from the previous year) is 10% prevalence in the whole population (Figure 13-A). It is also known that the disease is detected most frequently from adults than from juveniles (age = risk factor). Any increase of more than 5% prevalence would lead to implementation of a control program.

When designing the surveillance strategy with the goal of estimating prevalence, the best approach would be to conduct a survey based on a representative sampling (either a random sample or a stratified sample which takes into account the population proportion of each age group) (Figure 13-B.1). In this way, the prevalence in the sample ($2/20=10\%$) reflects the prevalence in the whole population ($10/100=10\%$).

On the contrary, if the sampling were focused only on the high-risk stratum (HR=adult animals) to reduce the sample size (Figure 13-B.2), then the prevalence of the sample ($3/15=30\%$) would have overestimated the prevalence in the general population and unnecessarily triggered a control program.

Best Practice Example 14. Representative sampling

FIGURE FOR BEST PRACTICE EXAMPLES 14, 15 AND 16



A. Baseline disease level during the previous year. Dark boxes (10) represent infected units and white boxes (90) uninfected ones. 60 units belongs to the low-risk (LR) and 40 to the high-risk (HR) group.

B.1. Representative sampling for current year. 20 units are scheduled to be sampled (circles): by selecting them at random, 12 come from the low-risk and 8 from the high-risk groups (i.e. proportional to the number of units in each group).

B.2. Risk-based sampling for current year. 15 samples are scheduled to be collected and all of them are allocated to the high-risk group.

Figure 13. Surveillance for describing the level of disease occurrence

5.2.3.3 To optimise case detection

In some situations, surveillance is designed with the primary goal to detect individual cases of disease to estimate the prevalence and to trigger mitigation action when disease is found. *Risk-based sampling approaches can therefore be applied to optimise case detection by focusing on strata at higher risk* of being infected or detected. This will increase the likelihood of detecting cases (i.e. the primary goal) but will generate non-representative data for the subsequent estimation of disease frequency (i.e. the secondary goal). Therefore, appropriate statistical methods must be applied to reduce the bias in prevalence estimates.

5.2.3.4 Making inference about disease prevalence from a risk-based sample

Making inference about disease prevalence from a risk-based sample *requires knowledge of epidemiological parameters* (see Textbox 3) that allow relating the prevalence in the general population with the prevalence in the study sample.

Textbox 3. Epidemiological parameters that are important when making inference about disease prevalence from risk-based samples

Risk Ratio (RR) is the ratio between the probability of disease in the high-risk group and the probability of disease in the rest of the population (the low-risk group).

The proportion of the population exposed to the Risk factor (F_r)

Once those parameters are known, one possible method to de-bias the prevalence estimation is to calculate the point value of the sample (Williams *et al.*, 2009). The *point value* represents the number of animals that should have been randomly selected from the entire population in order to achieve an equivalent inference. This value, computed from RR and f_r , allows to scale the estimated prevalence from the risk-based sample (i.e. which derived from the high-risk group) to derive the prevalence in the entire population (see [Best practice example 15](#)).

15

– SEE FIGURE 13

A surveillance program to detect cases of Bovine Viral Diarrhoea (BVD) is in place in a given country. The goal is to detect infected herds (= cases) to put them under restriction, with the auxiliary goal of estimating the prevalence of infected holdings to monitor the level of disease. From a survey carried out on the previous year, 10% of the cattle herds were infected (i.e. prevalence) (Figure 13-A) and cases are expected to be more frequent in the southern part of the country (geographical location = risk factor).

Under a first scenario, surveillance consists of an annual survey based on a representative sample of the population (Figure 13-B.1). This allows to detect 2 infected herds from 20 herds randomly sampled throughout the whole country and to estimate a prevalence of 10% (2/20), which reflects the prevalence in the whole cattle herd population (10/100=10%).

Under a second scenario, surveillance is designed over a risk-based sampling (Figure 13-B.2), in order to increase the probability of detection and reduce the sample size. This allows to detect 3 infected herds from 15 herds located in the southern part of the country (HR=south) and to estimate a prevalence of 20% (3/15), which reflects the prevalence in the high-risk area (8/40=20%), but not the overall prevalence. Therefore, the latter scenario is better suited to the main surveillance goal of detecting cases, but it overestimated the prevalence (i.e. secondary goal), while the first scenario was less effective in case detection but it produced unbiased estimates of prevalence.

Corollary to the second scenario: from previous studies it comes that the prevalence of BVD in the southern part of the country (HR area) is six time higher than in the north (LR area), meaning that the risk ratio is 6 ($RR = \text{prevalence in HR area } (P_{HR}) / \text{prevalence in LR area } (P_{LR})$, where $P_{HR} = 8/40 = 20\%$ and $P_{LR} = 2/60 = 3.3\%$). The proportion of the herds located in the south (HR) is known to be $40/100 = 40\% = f_r$. The point value for this risk-based sample can be calculated as $RR / [f_r \cdot RR + (1 - f_r)] = 6 / [0.4 \cdot 6 + (1 - 0.4)] = 2$.

This means that twice the amount of samples would have been needed if drawn at random from the general population in order to detect those three cases. The scaled prevalence becomes $3 / (15 \cdot 2) = 10\%$, as the prevalence in the whole population of cattle herds.

Best Practice Example 15. Making inference from high-risk group to population: the point value

5.2.3.5 Constraints of risk-based sampling for estimating disease prevalence

The need to acquire accurate epidemiological information (RR and f_r) is the main drawback associated with risk-based sampling for the estimation of disease prevalence. This is particularly challenging when the **DISEASE IS RARE** or the **KNOWLEDGE ABOUT THE POPULATION STRUCTURE IS VAGUE**. The more uncertain those parameters are, the less efficient the method to adjust for the selection bias is, because the correction will lead to an over- or underestimation of the prevalence of the general population (see **Best practice example 16**).

16

– SEE FIGURE 13

A surveillance program to detect cases of *Salmonella spp.* in cattle is in place in a given country. The goal is to detect infected herds (= cases) to put them under restriction, with the auxiliary goal of estimating the prevalence to provide evidence to the trading countries that the risk of disease is under control. During the previous year, 10% of the cattle herds were infected (i.e. prevalence) (Figure 13-A) and cases are expected to be more frequent in dairy herds (production type=risk factor).

Under a first scenario, surveillance consists of an annual survey based on a *representative sample of the population* (Figure 13-B.1). This allows to detect 2 infected herds from 20 randomly sampled cattle herds (dairy and beef) and to estimate a prevalence of 10% (2/20), which reflects the prevalence in the whole cattle herd population (10/100=10%).

Under a second scenario, surveillance is designed over a *risk-based sampling* (Figure 13-B.2), in order to increase the probability of detection and reduce the sample size. This allows to detect 3 infected herds from 15 randomly sampled dairy herds (HR = dairy) and to estimate a prevalence of 20% (3/15), which reflects the prevalence in the dairy population (8/40=20%), but not the overall prevalence.

A statistical method to correct the prevalence estimation will be used, but the epidemiological information needed to apply it (RR and fr) is uncertain. It is expected that the prevalence of *Salmonella* in dairy herd should be three times higher than in beef herds (RR=3) and that the proportion of dairy and beef herds is the same over the country (fr=0.5). The point value for this riskbased sample is calculated¹ as $RR/[fr \cdot RR + (1 - fr)] = 3/[0.5 \cdot 3 + (1-0.5)] = 1.5$. The scaled prevalence becomes $3/(15 \cdot 1.5) = 13\%$, which is higher than the prevalence in the whole population.

The conclusion based on this estimate will be that the prevalence has increased compared to the previous year (13% vs. 10%) and therefore trading countries might believe that the risk of *Salmonella* has increased, with possible consequences on the economy of that country.

Best Practice Example 16. Representative sample versus risk-based sample

Whenever the prevalence estimation will be used to inform further decision-making, even when it is not the primary goal of the surveillance, it is advisable to apply a representative sampling approach. Another possibility would be to adopt more complex statistical methods to take into account the uncertainty in the estimated *point values*. The statistical methods would be needed both during the design of risk-based surveillance (Wells *et al.*, 2009) as well as for the analysis of the sample results (Williams *et al.*, 2009).

Table 6 lists advantages and disadvantages of different surveillance components to help judge their suitability for establishing disease occurrence and trends.

Table 6. List of advantages and disadvantages using a surveillance component for estimating level of disease occurrence

| SURVEILLANCE COMPONENT | ADVANTAGES | DISADVANTAGES | RECOMMENDED |
|---------------------------|--|---|----------------|
| Passive disease reporting | Very high coverage, Low cost | Might suffer from reporting bias | Yes |
| Abattoir surveillance | High coverage, Low cost | Representative only of healthy population | To some extent |
| Sentinel herds | Not suitable for disease frequency estimations | Non representative | NO |
| Representative surveys | Representative | Can be expensive | YES |
| Risk-based surveys | Can be used to reduce sample-size without losing precision | Biased towards the high-risk population | To some extent |
| Syndrome surveillance | Not suitable for disease frequency estimations | Non disease specific | NO |
| Zero (negative) reporting | Not suitable for disease frequency estimations | Not applicable for diseases that are actually present | NO |

5.2.3.6 Summary

SURVEILLANCE TO MEASURE THE LEVEL OF DISEASE OCCURRENCE:

- could be carried out ad hoc (e.g. once) or periodically (e.g. once a year);
- should *preferably be based on a representative sampling* of the population to avoid bias;
- could be based on non-representative sampling if enough information is known about risk differences and population proportions;
- should use sufficient sample size to achieve an adequate precision in the estimates.

5.2.4 Present diseases - Detecting cases of disease

A disease is *endemic* in a population when it is maintained without needing external inputs. Priority might be given to **REDUCE OR ELIMINATE** a disease that is endemic. The actions to undertake to reach this will depend on the disease situation (i.e. prevalence and incidence) and its impact on animal and public health, food safety and farm economy (see Section 4.2).

5.2.4.1 Continuous and comprehensive surveillance

Disease mitigation programmes are often implemented with the aim of eventual disease elimination at a geographical area level, e.g. country, zone, compartment level. For some diseases, elimination may not be practically or economically feasible. But if aiming at this, both **CLINICAL CASES** and **THE PATHOGEN** should be eliminated from the population, at least theoretically. For this it is necessary to be able to detect cases (see also case definitions in Section 5.1). Surveillance for case finding assumes that cases might be present in the overall population, i.e. in every population stratum, albeit with different probabilities. Consequently it is important that the surveillance system

(components) cover the entire population. When surveillance for elimination of disease, activities are normally *continuous over time* (e.g. routine abattoir testing) and *preferably comprehensive* as they aim at finding as many cases as possible. From this follows that when the ultimate goal of surveillance is *to achieve disease elimination, risk-based surveys focusing only on the high-risk population stratum are not advisable*. By definition risk-based surveillance will disregard a part of the population, the low-risk part, where nonetheless (few) cases can still be present.

5.2.4.2 RISK-BASED SURVEILLANCE

Risk-based approaches can be applied *to increase the chances of finding cases, to enhance the efficiency and timeliness of case finding* surveillance. Here fore subpopulations at higher risk of being infected and/or detected need to be identified (see [Best practice example 17](#)). These high-risk strata of the population may be subjected to more stringent surveillance (e.g. higher sampling frequency) compared to the low risk-strata (see [Best practice example 18](#)). This can be applied for example *when the prevalence of disease is relatively low* (e.g. after a successful elimination programme has been in place for some years).

5.2.4.3 COMBINATION OF COMPONENTS

Full coverage of the population (i.e. animals and herds) is very hard to achieve, if not impossible. It is therefore *important to combine several surveillance components*, e.g. farm testing, abattoir surveillance, surveillance of fallen stock, in order to increase the likelihood that one individual/epidemiological unit will be covered by at least one component. To this regard, *passive disease reporting* plays an important role as a complementary component, being almost inexpensive and virtually comprehensive. It would be therefore advisable to always include such surveillance component in the design of a surveillance system for case finding.

In the design of surveillance systems aimed at case finding, different surveillance components may be combined. Table 7 presents a short list of advantages and disadvantages of several surveillance options to be possibly combined for case finding.

Table 7. Advantages and disadvantages of several surveillance components for case finding

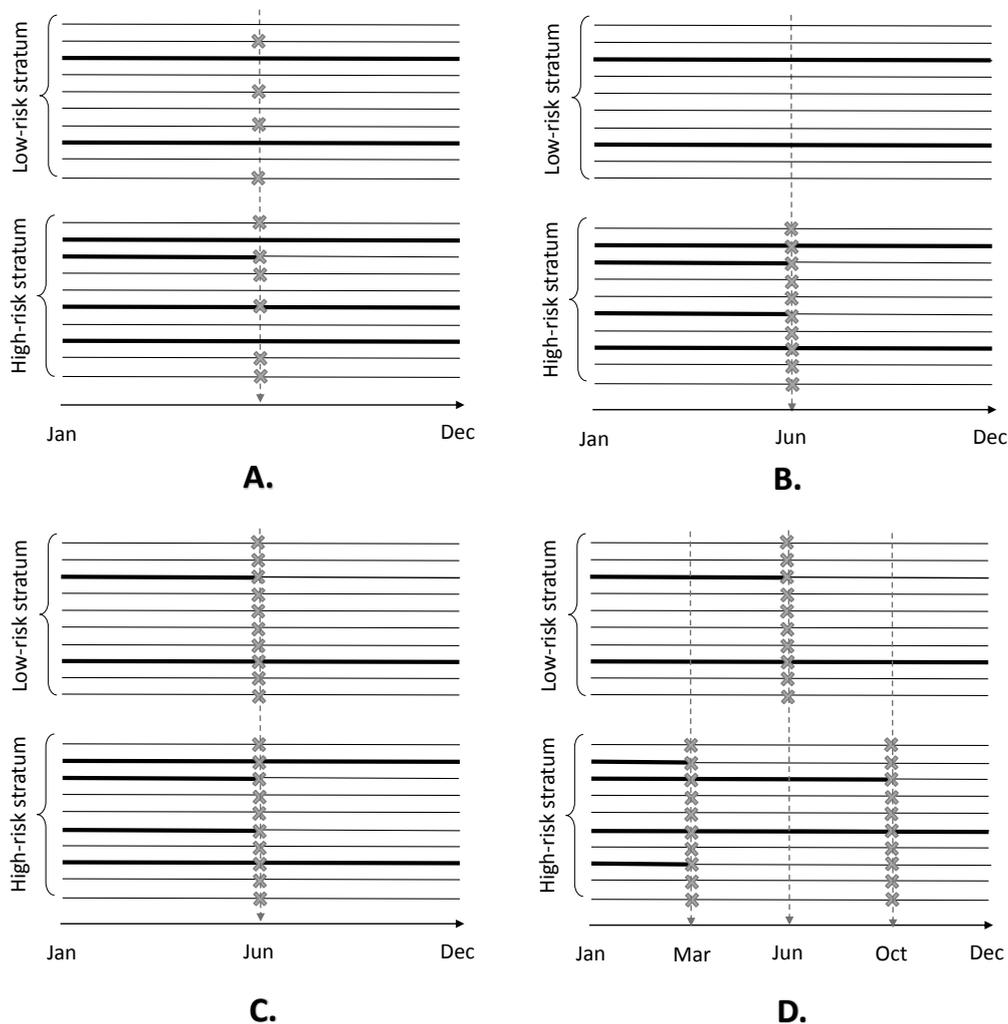
| SURVEILLANCE COMPONENT | ADVANTAGES | DISADVANTAGES | RECOMMENDED |
|---------------------------|--|---|----------------|
| Passive disease reporting | Very high coverage, low cost, on-going | Rely on farmers' knowledge and compliance | YES |
| Abattoir surveillance | High coverage, low cost, on-going | Representative only of the healthy population | YES |
| Sentinel herds | Early warning | Very low coverage | NO |
| Representative surveys | Representative | Low coverage, ad hoc | To some extent |
| Risk-based surveys | Higher chance to detect cases | Low coverage, ad hoc | YES |
| Syndrome surveillance | Early warning, on-going | False alarms | YES |
| Zero (negative) reporting | Not suitable for case-detection | Not suitable for diseases that are actually present | NO |

5.2.4.4 Summary

SURVEILLANCE TO DETECT CASES OF DISEASE:

- Could be *on-going* or *periodic* (if the infectious period is long or transmission rate is low);
- could benefit from risk-based approaches to focus on the population at higher risk of being infected and/or detected;
- should cover the whole population when the ultimate goal is disease elimination;
- should consist of *several (complimentary) surveillance components* to increase coverage.

SIMPLIFIED EXAMPLES OF SURVEILLANCE FOR CASE FINDING FOR BEST PRACTICE EXAMPLES 17 AND 18



Lines represent units over time. Bold lines represent cases. Crosses represent sampling points (i.e. units that have been surveyed at a certain point in time). Case finding capacity of the surveillance system is assumed to be 50%, meaning that on average every second infected unit is detected as a case. Once a case is successfully detected it will be removed from the population.

- A. **NON RISK-BASED SURVEY.**
- B. **RISK-BASED SURVEY** focusing on an extensive sample of the high-risk population.
- C. **NON RISK-BASED COMPREHENSIVE SURVEILLANCE** designed to investigate all the units of the population.
- D. **RISK-BASED COMPREHENSIVE SURVEILLANCE** designed to investigate all the units of the population with strengthened activities in the high-risk stratum.

NB. Comprehensive surveillance is achieved by combining different complementary surveillance components.

Figure 14. Simplified examples of surveillance for case finding

17

– SEE FIGURE 14

Surveillance for bovine tuberculosis in cattle is in place in a given country. *The goal is to detect infected animals (= cases) and remove them from the population*, as prescribed by the national control program. Due to economic constraints it is not possible to screen the entire population, but only a sample.

When the prevalence of disease is moderate to high, a *representative* sample of the population might be sufficient to detect cases and further remove them: see [Figure 14-A](#). - 10 units were sampled and 1 case was detected and removed. Prevalence was reduced from $6/20=30\%$ to $5/20=25\%$.

However, to optimize the resources, the samples might be focused only on the *high-risk group* (e.g. animals older than 6 months). This will increase the chances of detecting cases: see [Figure 14-B](#). – The sampling was focused on the high-risk group only. Out of 10 samples, 2 cases were detected and removed. Prevalence was reduced from $6/20=30\%$ to $4/20=20\%$.

Best Practice Example 17. High-risk strata

18

- SEE FIGURE 14

Surveillance for bovine viral diarrhoea (BVD) in cattle is in place in a given country. *The goal is to detect infected holdings (= cases) and put them under restrictions as part of the national eradication programme*. Being eradication the ultimate goal of case finding surveillance, it is desirable that all the cases will be eventually identified and removed from the population.

One approach could be design a multi-component surveillance system capable to cover all the cattle herds: see [Figure 14-C](#). – All herds were surveyed (20) by different surveillance components and 3 out of 6 cases were successfully removed.

Another approach could be to design a multi-component surveillance system capable to cover all the units of the population but with strengthened surveillance efforts in the high-risk stratum. Therefore, herds in the low-risk area of the country will be tested once a year, while herds in the high-risk area of the country will be tested twice see [Figure 14-D](#). – All herds in the low-risk group were surveyed once, detecting 1 out of two cases. All herds in the high-risk group were sampled twice, detecting 3 out of 4 cases.

The second approach requires more resources, but it will allow achieving eradication in a shorter time.

Best Practice Example 18. Low-risk strata

5.3 TOOLBOX 5

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TOOLS

RISKSUR SURVEILLANCE DESIGN FRAMEWORK :

The RISKSUR design framework was developed to provide support and tools to enable users to identify more precisely the characteristics of the surveillance system described above before going on to design individual components. It provides:

- Decision tree to guide the user to the appropriate tool to use
- Guidance on how to use @Risk or epitools for risk-based requirements
- Advice on the advantages and disadvantages of different tools
- R packages: RSurveillance, FFD
- Epitools calculators <http://epitools.ausvet.com.au/content.php?page=home>
- Tools for scenario tree models: @Risk, code template for R Cran

How to obtain access: <http://www.fp7-risksur.eu/news-events/risksur-surveillance-design-framework-available>

Presentation of the framework (recorded webinar): via RISKSUR website <http://www.fp7-risksur.eu/news-events/surveillance-surgery-n°5-risksur-surveillance-design-framework> or directly:
<https://collab.switch.ch/p8n84dqsepu/?launcher=false&fcsContent=true&pbMode=normal>

Training how to use Surveillance Design Framework:
<https://accelopment.adobeconnect.com/p5sty0i73kh/?launcher=false&fcsContent=true&pbMode=normal>

Training and webinars on design related topics: <http://www.fp7-risksur.eu/progress/training-and-webinars>

6 IMPLEMENTATION

6.1 ROLES AND RESPONSIBILITIES

A few important aspects that will help a surveillance system run smoothly are linked to earlier mentioned stakeholder involvement (see Section 3.4), political support (see Section 3.1), and to how smoothly its implementation runs. A few important aspects of the implementation include ensuring that roles and responsibilities are clear (this section), that training is provided if and when needed (see Section 6.2), and that the flow of information and communication is appropriate (see Section 6.3). These were agreed upon during the prioritisation and planning phases and documented in the plan (see Chapters 3 and 4).

These roles and responsibilities relate to the actual work to be done to keep the surveillance system active and reactive, in terms of data and information sharing, notifications and feedback, disease mitigation measures, and adherence to legal and regulatory frameworks, both nationally and internationally.

The responsibilities in the implementation will also depend on the general organisational structure of the competent authorities and the decision-making processes that are commonly applied to coordinate stakeholder activities (See [Best practice example 19](#)).

19

The Veterinary Services of Switzerland are organised according to the country's federal structure. This is also reflected in surveillance roles and responsibilities.

The *cantonal veterinary offices* (i.e. lower-level administrative units) are responsible for case detection and reporting of cases as well as operational management of outbreaks, if there should be any. Their role is quite practical as they have official veterinarians in the field who have also got the right to access farms, if needed. There may be minor differences in the implementation of surveillance activities at cantonal level which should not impact on the coverage or comparability of results.

Surveillance efforts are *coordinated at federal level by FSVO* who is providing the legal basis for surveillance implementation.

Furthermore, there is a list of *reference laboratories contracted at national level* and a list of other recognised laboratories licensed to operate as part of official surveillance.

Surveillance activities are planned and implemented using an annual administrative cycle. Decisions are taken through the "Conference of Cantonal Veterinarians" where FSVO and the cantons are represented. Communication of surveillance results is assured by FSVO using mostly electronic means including annual reports and a searchable database of reported cases. Reporting duties towards the European Commission and to the OIE are also assured by FSVO.

Best Practice Example 19. Federal food safety and veterinary office (FSVO, Bern, Switzerland)

6.2 TRAINING AND RAISING AWARENESS

The actors playing a role in the surveillance system should be provided with the training needed to ensure the surveillance system can run efficiently. *New* and *additional* training should be provided according to the need suggested from the monitoring of the system's performance indicators. The training should make sure that everybody involved is *competent* and *has access to all the information and means* needed to perform their respective activities well.

Persons should receive *specified* training according to their tasks and responsibilities within the surveillance process. For instance, training should be provided on:

- how to interpret the case definitions,
- how to detect and interpret clinical signs,
- how to collect specimens for sampling,
- on the procedures of data collection,
- confidentiality,
- information sharing,
- frequency of analysis of data,
- reporting,
- who will take action in which situation.

Simulation exercises could also be envisaged once the surveillance system is already in place, to check if everybody knows his/her roles and responsibilities.

TRAINING OPTIONS - There are multiple ways to provide training. A "*train the trainer approach*" is recommended for multiplication and exponentiation of the dissemination of information. With this approach, those that get trained are expected to get the knowledge and tools necessary to pass the information on to others involved.

Training should ideally be conducted *in person*, dedicated to specific target groups. It can be delivered in different formats, e.g. workshops. Organising joint *face-to-face events* for animal handlers, owners and industry will provide opportunities to openly communicate and for answering questions. Yet, organising such meetings can be demanding in terms of financial and time resources. Therefore, the possibility of using online tools could be considered. FAO and other organisations have developed several *modular e-learning training programs* to be used *off- and online* but also as *(downloadable) support materials* for face-to-face training (See *Best practice example 20*). Another way to provide online training in shorter but more interactive format can be through *webinars*. Those are recordable and can be shared with everybody who is interested.

A way to *keep people informed* and *to conduct discussions* can be through a dedicated website or a chat-group. Although not a surveillance system, the RISKSUR project, for example, kept a *LINKEDIN GROUP* where information was regularly posted and shared.

RAISING AWARENESS – For farmers and the general public, a general information campaign can be conducted and animal owners/farmers/industry meetings can be used to inform specific target audiences on why reporting to veterinarians in certain situations is important.

For disease awareness, *flyers* can also be very useful materials. The language used should be adapted to the different expected audiences, as they will need, for example, more or less background information and might be expected to understand a different degree of details. Umbrella organisations (like for example the different professional associations in a country or

region) are usually a good resource when it comes to the dissemination of flyers. If the surveillance covers different language zones, it is also recommended to have the flyers translated into the most relevant local languages.

Occasions might exist where an extra **INCENTIVE** is needed to ensure that farmers, animal handlers, or the general public will report on suspected cases seen. This can particularly be the case when reporting can result in loss of animals and capital. It is crucial that animal owners and handlers understand their responsibility to report and adhere to procedures in the bigger picture. Negative consequences of reporting – financial or otherwise – should be avoided.

20

- **RISKSUR**

Under the RISKSUR dissemination tasks, several webinars were organized and delivered. Some were the so called “surveillance surgeries”. These were 1.5h webinars, where experts on a specific topic were invited to make presentations, which we followed by discussions. Topics covered included, for example: African Swine Fever (ASF), Avian Influenza (AI) or (surveillance of) Antimicrobial Resistance (AMR) and the design and evaluation tools.

- **ASFORCE**

Under the (EU FP7) ASFORCE project (asforce.org), several training workshops were organized. A disease awareness flyer was prepared, and translated into different languages.

- **EU-FMD**

Under EU-FMD several hands-on and e-learning trainings were developed and provided.

Best Practice Example 20. Some european projects that produced training material

6.3 DATA MANAGEMENT AND INFORMATION SYSTEM

Each surveillance system is based on the collection, validation, management, analysis and exchange of data and information between the different stakeholders, to inform those who need to know for taking appropriate and timely actions.

The methods used to handle data and information should be coherent with the surveillance objectives and activities of all the actors within the system. They should provide all the information needed, in a clear and up-to-date manner, to establish an effective and efficient data quality verification system and a proper continuous monitoring of surveillance performances and results.

How data and information are handled and how it flows can be called the **INFORMATION SYSTEM**. Very often however, this term is indicating the methods and tools applied *to handle the data*: data management, storage and sharing are part of a data management and information system. Such a system can be **AUTOMATED OR NOT**, using readily available or specifically designed standardised forms and templates or tools with interfaces including mobile phone applications and coded SMS messaging for data entry (See Madder et al., 2012). When automated, readily available or custom designed software programmes can process, store and analyse the entered or uploaded data. Automated algorithms and on demand data analysis will provide the users with the information that

can be shared and acted upon when needed and can be programmed to issue automated prompts when certain thresholds are reached. Templates for data sharing and reporting can facilitate the process of information sharing.

In most situations, **COMPREHENSIVE SYSTEMS** (i.e. all use the same system to enter their part of information/data) are not or not fully implemented. Therefore, integration efforts are needed to assure the inter-operability among systems as more and more automated data management and information systems allow for the gathering of data collected and stored by other automated sources. The central storage or dynamic access and linking of data from different surveillance systems can be achieved in a **DATA WAREHOUSE**. Data sharing also entails the establishment of common dictionaries, data standards, metadata, and rules for data exchange. The organisational structure of the institutions involved should be respected when the data flows (data inputs and outputs) are designed. Particular attention should be paid to these aspects when an animal health information system has to collect and manage data deriving from several competent authorities. It is crucial to ensure that the information system respects data ownership and confidentiality, and that all data is handled and stored securely.

It is recommended that all users have access to working protocols and training for data collection, collation, verification, registration and analysis that includes detailed definition of the information flows on the basis of the information debts and credits of each level, and the roles and responsibilities of each involved “actor”. (See section 4.3). The type of in- and output formats and frequencies of exchange must be approved and used by all authorities and stakeholders involved. Data safety, security and confidentiality need to be considered.

6.4 REPORTING AND INFORMATION DISSEMINATION

There are several flows of information in an animal health surveillance system. When the regular flow of **INTERNAL REPORTING AND FEEDBACK** runs smoothly, every stakeholder will receive and provide the information needed and linked to their respective activities roles and responsibilities. Also, frequent and updated information on the progress of surveillance itself, the performance indicators (see Chapters 2 and 7) will inform about when to take corrective decisions if needed. Besides the internal reporting and feedback mechanisms, it is important that **DESIGNATED AUTHORITIES AND A WIDER PUBLIC** will be informed on the outcomes of surveillance actions.

Some decision-makers require more elaborated data analyses for evaluating the extent of objectives achievement and performances of surveillance system to take appropriate decisions for re-planning further surveillance and control actions. Other stakeholders and actors outside the central focus of the surveillance system should also be informed on the main outcomes of the actions, according to their needs and interests.

National and international legal frameworks and regional or bi-lateral agreements require that for certain animal diseases, designated legal or authoritative bodies need to be informed

The information has value at many different levels – potential users include livestock owners, owner groups, co-operatives, or enterprise industry bodies, private veterinary services, agricultural product manufacturers, local, provincial and national government veterinary authorities, legislators, university and research organizations, trading partners, regional or international organizations (see **Best practice example 21**). Several means of communication can be considered (see Table 8).

Table 8. Communication means in animal health surveillance serving different groups and purposes

| TO WHOM/WHY | WHY | WHAT | HOW |
|--|--|--|--|
| Services and people actively involved in the surveillance system (component) | To serve the objective of the surveillance system (component) | Detailed data, results and other information | Data management and information system, webtools, regular technical bulletins, newsletters |
| Designated authorities | To notify or report, to adhere to international and national regulations and obligations | Indicated specific disease status or events | Appointed routes (see for instance OIE for OIE listed diseases) |
| Stakeholders | To inform them and maintain their participation | Summaries, highlights or details on the output of the system in a certain time-frame and or geographical area for instance | Regular technical bulletins, newsletters |
| General public | To inform | Press releases, news items | Webtools, media |
| International community of health professionals, researchers, policy makers, will be of value for a large group: | To inform and apply | The lessons identified | Articles in peer reviewed journals, presentations at meetings, conferences |

21

In the Netherlands, the reporting of the surveillance results is done quarterly in meetings with the stakeholders of the Monitoring and Surveillance program in the form of presentations and a written report. When needed stakeholders are informed about findings by e-mail or telephone instantly. Given that all information comes from farmers and veterinarians much care is taken in informing them about the findings in the Monitoring and Surveillance program. Information to farmers is disseminated via the GD website and in quarterly magazines from GD Animal Health. Veterinarians receive monthly newsletters in which relevant surveillance information is shared, information is regularly published in a national magazine for veterinarians and information is disseminated via the GD website. In addition, an information leaflet and a year report is distributed to a large group of policymakers, stakeholders and (inter)national contacts.

<http://www.gdanimalhealth.com/monitoringsurveillance>

Best Practice Example 21. Quarterly reporting in the Netherlands

6.5 TOOLBOX 6

REFERENCES

WEBSITES:

SWEDEN DIGITAL REPORTS - <http://www.sva.se/om-sva/publikationer/sjukdomsovervakning/surveillance-of-zoonotic--other-animal-disease-agents-in-sweden1>

RISKSUR TERMINOLOGY – <http://www.fp7-risksur.eu/terminology>

UK GOVERNMENT PUBLICATION ON CONTROL STRATEGY - <https://www.gov.uk/government/publications/notifiable-avian-disease-control-strategy-for-great-britain>

FAO E-LEARNING – <http://www.fao.org/elearning/#/elc/en/home>

EU-FMD E-LEARNING - <https://eufmd.rvc.ac.uk>

RISKSUR LINKEDIN GROUP - <https://www.linkedin.com/grp/home?gid=5029768>

RISKSUR WEBINARS - <http://www.fp7-risksur.eu/progress/training-and-webinars>

ASFORCE - <http://asforce.org/training> including an online course: <http://asforce.org/course>

PEER-REVIEWED PUBLICATIONS:

Iannetti S. et al., 2014, . An integrated web system to support veterinary activities in Italy for the management of information in epidemic emergencies. Preventive Veterinary Medicine, 113, 407–416.

Madder. M., et al., 2012, e-Surveillance in Animal Health: use and evaluation of mobile tools, Parasitology, 139(14):1-12. DOI: 10.1017/S0031182012000571

7 EVALUATION AND PERFORMANCE MONITORING

Evaluation
ex ante

Performance
monitoring
in itinere

Evaluation
*in itinere and/or
ex post*

7.1 OBJECTIVES

The (re-)planning and (re-)designing of a surveillance system (component) should include a plan for evaluation and monitoring activities to ensure that the system remains flexible to change. It needs to be adaptable to changes linked to one or more of its drivers, e.g. epidemiological, biological, ecological, economic, social, cultural, political and environmental factors. Evaluation provides advocacy elements, for changes of the system *ad hoc* (fine tuning) or to a larger extend for (re-)planning and (re-)design or to end the activities (exit), and success stories to inform good practices.

The main objectives of performance monitoring and, process and effectiveness, evaluation of a surveillance system are the same: *to inform on the capacity of the surveillance system to generate its outputs and address its objectives, and to allow for timely implementation of corrective actions* (See Textbox 4).

Textbox 4

OBJECTIVES OF THE EVALUATION OF SURVEILLANCE SYSTEMS¹:

1. To inform the design and re-design: to facilitate choice between different options; to identify alternative options. E.g. to improve the system, to compare different design.
2. To inform local decision makers optimisation of resource allocation: balance between performances/improvement of the system and resources involved.
3. To inform local decision makers choice between different animal health management programmes: benefit of the system for the society.
4. To provide information on the quality of the surveillance data generated, and real disease situation.
5. To inform trade regulation authorities: quality of the surveillance data and real disease situation.
6. To ensure stakeholder trust is obtained: at local and global level; effect on sustainability and efficiency of the system; "to ensure trust and keep trust"

¹ Workshop results SVEPM 2015 Belgium

Continuous monitoring of the **performance** of the system or one or more of its component(s) *using performance indicators* (see Section 7.2) will provide insight into whether the activities are being carried out according to plan and allow making *ad hoc* adaptations as needed. At fixed moments in time before, during and/or after the start of the activities (re-)evaluation of effectiveness and efficiency can be done. **Effectiveness** evaluation will be done applying *process and effectiveness*

evaluation attributes of the surveillance system (see Section 7.3). Similarly, efficiency evaluation will apply economic assessment criteria and methods (see Chapter 8).

Because evaluation can be a timely and costly process, comprehensive evaluation of the entire system or its components is almost never done. Hence it is important to define evaluation objective(s) specifically to focus related methods and activities (see Textbox 4). Formulation of specific and detailed evaluation question(s) will indicate which evaluation methods and activities can be applied to answer these questions. The scale and timing of the evaluation activities will thus depend on the objective and evaluation questions.

The RISKSUR project developed the EVA-TOOL that will guide planners of evaluation in formulating (a) specific evaluation question(s) and indicates towards appropriate methods to apply (see Toolbox Chapter 7)

Table 9 shows that the main differences between performance monitoring and evaluation tasks lie in:

- TIMING: moment relative to the surveillance system and frequency of the action
- SCALE: number and extend of elements (see Section 7.3) and surveillance attributes considered in the tasks
- INFORMATION generated by the activity: reporting on the action outputs

Table 9. Differences between performance monitoring and evaluation of surveillance systems (components)

| | PERFORMANCE MONITORING | EVALUATION | | |
|---|---|--|---|--|
| Timing - Moment | <i>(In itinere)</i> While in place and running (implementation) | <i>Ex ante</i> To inform design (before implementation) | <i>In itinere</i> While in place and running (implementation) | <i>Ex post (Rare)</i> After the end of the system (after implementation) |
| Timing - Frequency | Continuous | Momentaneous | Momentaneous Once or at Regular intervals (f.i. yearly) | Momentaneous |
| Scale (depending on evaluation objectives) | Many elements and attributes covering all priority objectives | One to all elements and attributes | | |
| Information | For continuous <i>ad hoc</i> improvement/fine-tuning of the system Inform the evaluation | On the system's ability to meet its objectives, i.e. the quality of the information generated by the system Inform decision makers on how to optimise Inform on how sustainable and acceptable the system is For specific purposes: for instance ensuring access to international markets | | |

As shown in Table 9, EVALUATION can be performed *ex ante* (i.e. before the implementation of the system), *in itinere* (i.e. while the system is in place and running) or *ex post* (after the end of the system). Surveillance systems are rarely terminated, therefore *ex ante and in itinere are the most commonly applied moments for evaluation in animal health surveillance*. Table 10 provides a link between timing and surveillance objectives.

Ex ante evaluation - could be performed to provide essential elements for the design and planning of the surveillance system. E.g. epidemiological models could be used to evaluate which sampling protocol will ensure highest effectiveness of the system and therefore inform on the sampling design; *participatory* studies to assess the local constraints and the acceptability of surveillance could be implemented to select between different organisation options.

In itinere evaluation - implies regular evaluation moments of the surveillance system (components), e.g. annually; every two years; as needed. The timing for evaluation will depend on the purpose of surveillance, objective of the surveillance system (component), and on **specific trigger points** such as the evolution of the disease situation. It can assess its performances and its added value. When done with regular intervals, it provides information on process efficacy and data output. Already when planning the system and its evaluation it is good to include those elements that will trigger undertaking evaluation, for examples see Textbox 5.

Ex post evaluation - can be implemented to identify lessons to be learned from the implementation and running of the surveillance system (component). The surveillance system (component) could have been exited due to sustainability issues or because the disease was eradicated (e.g. rinderpest).

Textbox 5

DIRECT OR INDIRECT¹ TRIGGER POINTS FOR EVALUATION OF A SURVEILLANCE SYSTEM²

- Change in local disease situation, e.g. increase in outbreaks number, incursion of disease
- Change in disease control options
- Change in surveillance design, e.g. introduction of novel surveillance component
- Public health issue
- Change in neighbouring countries, international disease situation, e.g. increase in risk of introduction
- History of surveillance and timing since last evaluation
- Political request, legislative requirement
- Risk awareness perception issue , society perception
- Trade requirements
- Socio-economic context, e.g. reduction in budget triggers need for improve resources allocations and cost optimisation

¹ Those points could be interlinked

² Workshop results SVEPM 2015 Belgium

Table 10. The link between evaluation timing and objectives (Calba et al. 2015)

| STEPS OF THE OBJECT UNDER EVALUATION | EX ANTE | IN ITINERE | EX POST |
|--------------------------------------|---|--|--|
| PLANNING | Expected outputs, incomes, impact | | |
| DESIGN | How to reach the outputs, outcomes, impact | | |
| IMPLEMENTATION | What to do to reach the outputs, outcomes, impact | Which outputs, outcomes, impact were reached <i>and/or</i> Required outputs, outcomes to reach the impacts | |
| RE-DESIGN; RE-PLANNING | | What to implement to reach the missing/new outputs, outcomes, impact | Which outputs, outcomes, impacts were reached. What went wrong/right; what should be done/corrected in a new process (lesson learned) |

7.2 PERFORMANCE MONITORING

7.2.1 Planning

Continuous monitoring of the performance of a surveillance system (component) will provide information on the efficacy of the system to generate its outputs and therefore allows for timely implementation of minor adaptations and corrective actions. When a well-designed surveillance system (component) performs well, timely intervention can be implemented to mitigate the consequences of disease and waste of resources can be avoided.

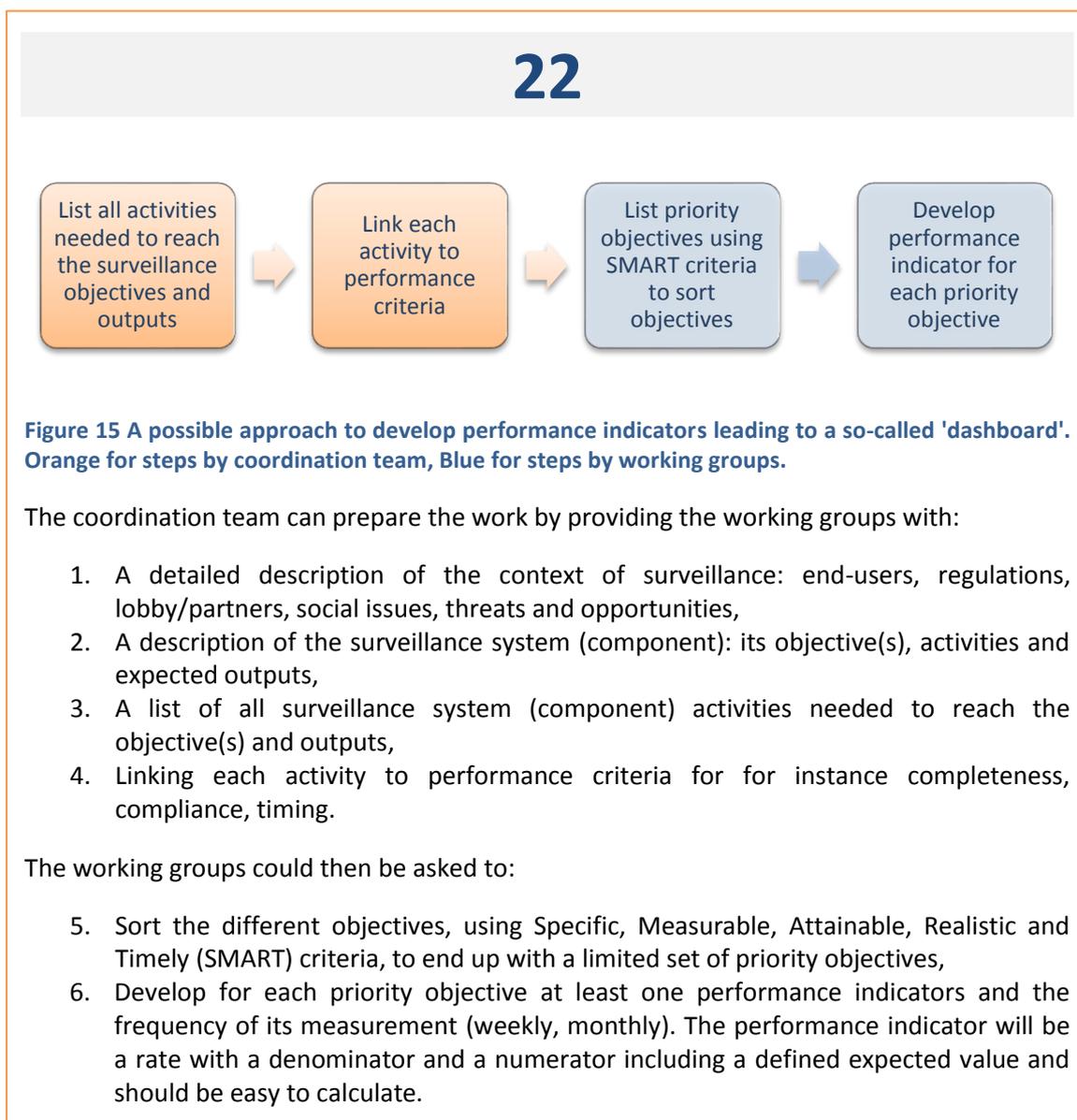
To monitor the surveillance system (or one of its components) a set of *performance indicators* (see Chapter 2) is needed. They need to be selected during the design stage and can only be set once the surveillance objective(s) and surveillance protocols have been formalised and accepted by the surveillance coordination team.

PERFORMANCE INDICATORS are variables for which quantitative and qualitative data *on the surveillance system process* will be generated continuously. They therefore inform on *the quality of the data generated by the surveillance system (component)*, e.g. on data management, quality of data records. Furthermore, those data are the key elements to assess for the evaluation of the *process* and *effectiveness* of the surveillance system (component).

7.2.1 Selection of performance indicators

Those involved in the design of the surveillance system (component) select the performance indicators. While led by the network coordinator or the coordination team, it is advisable to involve all the actors in the system (component), i.e. all stakeholders.

Crucial for ensuring selection of relevant performance indicators is that they provide practical enhancement of the surveillance system (component) operation and not a constraint. A possible way to ensure involvement of all is to create working groups with representatives of stakeholders and the coordination team, for instance in the way as is shown in [Best practice example 22](#).



Best Practice Example 22. Stakeholders selecting performance indicators

7.2.2 Implementation of performance monitoring

Once the performance indicators have been selected, it should be ensured that the stakeholders accept them. If not all of the stakeholders were represented during the selection of the performance indicators; it might be advisable to communicate to all in order to reach acceptability and compliance.

The performance indicators can be organised in a dashboard (see also [Best practice example 22](#)). If the dashboard can be connected with a database where all the information for the numerators and denominators is gathered, calculation of the performance indicators could be automated. The information in the database could be coming directly from the surveillance database, or should be collected as needed. If calculation is automated the team could be prompted automatically once anomalies of the expected are detected.

The coordination team, or one of them, will be responsible for the performance monitoring. The performance indicators will be calculated according to an own set frequency, and diagnostic indicators can be calculated when threshold values are not reached.

The coordination team will use the performance indicators and diagnostics to review and modify the surveillance protocol in order to improve the functioning and the operation of the surveillance system (component). If the surveillance system activities need to change, it might be needed to provide additional training to the stakeholders involved. Following changes to the surveillance protocols, performance indicators themselves might need to be updated as well.

Performance monitoring in itself serves as a feedback mechanism to stakeholders and is important to achieve the objectives of the system (see [Best practice example 23](#)).

23

GD Animal Health runs a telephone consultancy service for veterinary practitioners and farmers where they can report and get feedback on animal health problems that they encounter on the farms. The consultancy service, called 'GD Veekijker', functions as a passive surveillance component in the national animal health surveillance program.

All phone calls are registered in a central database. Each quarter of the year the stakeholders of the surveillance program receive information about the number of calls and how these correspond to the trend in time in the previous years. Deviations from the normal variation are investigated through more in-depth analyses of the subject matter, spatio-temporal cluster analyses and/or contacting veterinarians.

Once a year, more detailed analyses are carried out to monitor the representativeness of the signals derived from the surveillance component.

Quality indicators are for example the proportion of veterinary practitioners that contacted the service, how the number of calls is related to farm densities, whether the number of calls per veterinary practice is influenced by the size of the veterinary practice, and whether all regions in the Netherlands are covered.

Best Practice Example 23. Performance (or quality) indicators for passive surveillance in the Netherlands

7.3 EVALUATION

7.3.1 Planning

The planning and design of evaluation and monitoring ideally coincides with the planning and design of the system (components) itself. The suggested steps to follow are described here. However, in reality, evaluation is often considered later. If this is the case, the suggestions will need adapting. The purpose is to come up with a comprehensive, practical, and affordable evaluation plan for timely assessment of not only the effectiveness, benefits and costs (see Chapter 8 for costs) of a surveillance system, but also the factors that influence the effectiveness of the system. For this *functional evaluation attributes* are used. Those should include attributes required for evaluation of local acceptance, which is crucial to ensure the effectiveness and sustainability of the system at national and international levels. Participative methods could be applied for this purpose (See [Best practice examples 24, 25, 26](#)).

STEP 0. PLAN YOUR EVALUATION - DURING PLANNING STAGE

Define:

- The evaluation objective (evaluation question could be specified at a later stage);
- The frequency and budget allocation for evaluation;
- The evaluation trigger points (consider those provided in Section 7.1);

And:

- Plan extra budget to address any additional evaluation needs.
- Review your evaluation plan after every evaluation.

STEP1. DEFINE YOUR EVALUATION PROTOCOL – DURING DESIGN OR IMPLEMENTATION

(During the design stage for *ex ante* evaluation; just before performing the evaluation for *in itinere*)

- Define the evaluation question, which depends on the actual context. The EVA-tool developed under RISKSUR will guide towards specific formulation of evaluation questions (See Toolbox Chapter 7)
- Frame the evaluation protocol. This will relate to the evaluation question: decide if the evaluation will be at the component or system level (see Section 7.3.2) and decide which elements to include in your evaluation, i.e. which evaluation attributes, which economic criteria (See Chapter 8).
- Select the attributes that will be assessed according to 1) the evaluation question; 2) the data available and/or availability for additional data collection; 3) available resources and competences (See EVA-tool, Toolbox Chapter 7)
- Select the appropriate methods to assess the evaluation attributes and economic criteria if relevant, according to 1) the data available or availability for additional data collection; 2) available resources and competences (See EVA-tool, Toolbox Chapter 7)

STEP 2. PERFORM THE ASSESSMENT

The timing of Step 2 will be defined in Step 0 and could vary according to trigger points, and will include:

- Data collection (if required)
- The assessment of evaluation attributes and economic criteria.

STEP 3: ADDRESS EVALUATION QUESTION AND PROVIDE RELEVANT RECOMMENDATIONS.

An evaluation report will be prepared to compile all the information relevant to the evaluation process, including general context, justified evaluation question, justified choice of evaluation attributes and assessment methods, means of data collection (if required), outputs of the

assessment, interpretation of the outputs addressing the evaluation question and relevance of the evaluation results according to the evaluation question and specific context (including limits in the evaluation protocol and implementation if any).

Ultimately evaluation should lead to a judgment of the system and/or recommendations to strengthen it. Whether this is included in the report or will result from this is not crucial.

7.3.2 Elements of evaluation

There are several different angles wherefore or wherefrom to evaluate a surveillance system or one or more of its components. These elements can be:

PROCESS (OR FUNCTIONAL) EVALUATION

There are several reasons to assess whether the surveillance system (components) function as was planned or whether the activities should need fine-tuning.

Evaluation of the process of the system or component itself can provide a greater understanding of the systems organisation and provide meaningful recommendations and priority for corrective actions. It can also provide information on corrective actions to be implemented after a change in surveillance protocols will be implemented and for identification of the changes that occurred from a change in surveillance design (to inform cost analysis).

Process evaluation can also be applied both to assess the trust of stakeholders in the system, and to enhance it by application of participative methods (See [Best practice examples 24, 25, 26](#)).

24

Acceptability has been defined as the ‘willingness of persons and organisations to participate in the surveillance system’ and refers to the degree to which each of these users is involved in the surveillance. It reveals important perception factors and sociological aspects due to the fact that reporting an outbreak may be conflicting economic, cultural, and/or political incentives.

The objective of AccEPT is to engage representatives of all types of stakeholders of the surveillance (e.g. farmers, hunters, veterinary services) through individual face-to-face interviews or through focusgroup discussions. Each interview consists of three steps.

STEP 1 - Identifying surveillance system stakeholders’ professional network and assessing the satisfaction of the relations among them, through the elaboration of relational diagrams and the use of smileys.

STEP 2 - Representing the information flow within the system and assessing the trust devoted to fulfil its objective(s), with the use of flow diagrams associated with proportional piling.

STEP 3 - Assessing the satisfaction of the information flow (i.e. positive and negative impacts following a suspicion), with the elaboration of impact diagrams associated with proportional piling.

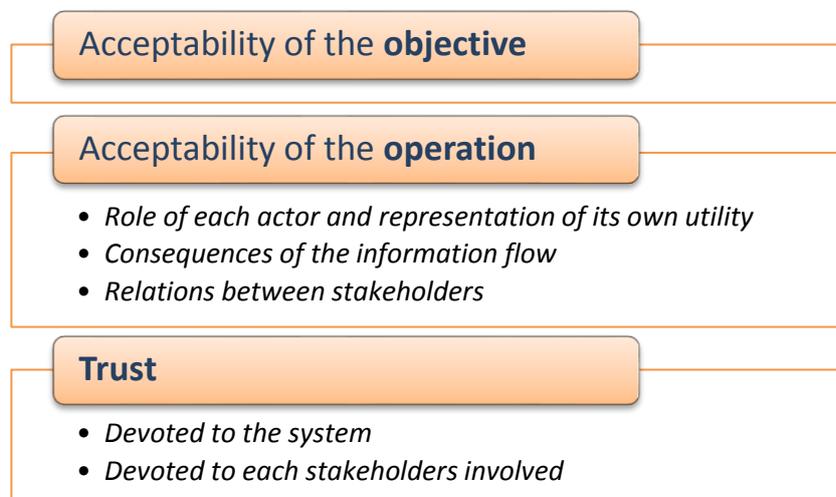


Figure 16 AccEPT was developed for stakeholder participatory evaluation of a surveillance system, by scoring criteria on acceptability of the objective and the operation of, and the trust placed into, it.

A scoring system has been developed in order to provide a semi-quantitative level of acceptability. Five criteria related to the acceptability of the surveillance objective(s), the way the system is operating, and the trust placed into this system, will be scored based on the information collected during the interviews using discussions, diagrams, smileys and proportional piling results. The score will be on a scale from -1 for low acceptability, to +1 for good acceptability. The level of acceptability can be calculated at every desired level, either for one specific type of stakeholders or for all actors involved in surveillance.

25

Germany is officially free from classical swine fever (CSF) since 2012; the last case in wild boar was detected in 2009. To be able to demonstrate freedom from disease on a regular basis, hunters play a key role. They are asked to collect samples from wild boar and to deliver them to the appropriate authorities. In Germany, most of the hunters are private persons who are not getting paid for these tasks. If the hunters are not willing to support a specific surveillance strategy, its implementation can be very difficult or even impossible. Hence there is a need to assess the acceptability of this surveillance system, especially for the hunters.

The AccEPT method was applied as a participative manner to obtain the opinion and needs of the hunters on several topics related to the CSF surveillance of wild boar and on possible alternative surveillance strategies. Twenty eight hunters worked with this method and were interviewed. Some of the main points that came out are listed here:

- More communication between the different stakeholders would be advantageous
- Hunters appreciate the chance to say their opinion
- A directive regarding passive surveillance would not be realisable
- The trust of the hunters in the conventional system is big, mainly due to the argument that the past showed that it works
- Cost reimbursement for the hunters could result in better surveillance output

In conclusion, through the use of the AccEPT method it was possible 1) to get a deeper insight in the opinions and the needs of the hunters, 2) to reach acceptability of the surveillance system through ensuring the hunters have a voice that is being listened to.

Best Practice Example 25. AccEPT method for classical swine fever surveillance in wild boar in Germany

26

Belgium is officially free from bovine tuberculosis (bTB) since 2003, but some sporadic outbreaks remain. To ascertain each outbreak will be early detected, there is a need to assess the acceptability of the surveillance system in place.

Thirty-four stakeholders from different backgrounds were interviewed using AccEPT. The figure below represents the level of acceptability of each stakeholder group for the three main component criteria of the overall surveillance system: 1) the objective(s) of surveillance (early detection), 2) the way the surveillance system is operating, and 3) the trust placed in the surveillance system.

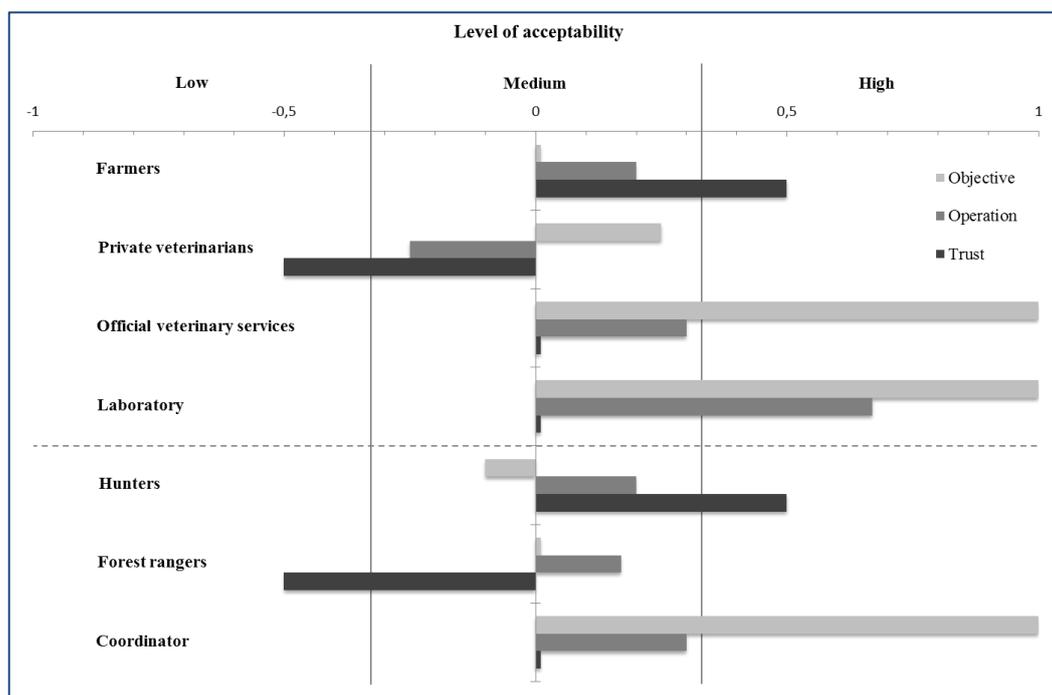


Figure 17. Example of outcomes of scoring with AccEPT for the surveillance of bovine tuberculosis in Belgium

Private veterinarians and forest rangers are key stakeholders, acting at the frontline of the system. The use of AccEPT allowed us to highlight the important issues preventing them to fulfill their role in the surveillance system. This method allowed discussing their perception of the current surveillance system and therefor to obtain more information on the general context withing which the surveillance is implemented. Taking their expectations into consideration allowed to develop a relationship of trust and to reach a stronger level of acceptability for the evaluation process itself. This exercise made it possible to propose context-dependent recommendations and to adapt the process of evaluation .

The main recommendations that came out from this participatory process were:

- To implement restraining systems for cattle in farms to facilitate private veterinarians work;
- To involve the veterinary services in the field for the implementation of tuberculin skin test, to facilitate the communication with farmers;
- To increase the material and financial resources for forest rangers, to be able to collect and preserve found-dead animals and bring them to the diagnostic laboratory.

Best Practice Example 26. AccEPT method for the bovine tuberculosis surveillance in Belgium

EFFECTIVENESS EVALUATION

Effectiveness evaluation involves *functional and effectiveness evaluation attributes* described in OIE manual and elsewhere (Drewe et al. 2013). Methods for the assessment of these evaluation attributes are described in the OIE manual, by Drewe et al, and the review by Calba et al. (2015) and can be found via the EVA-tool.

27

Germany is officially free from classical swine fever (CSF) since 2012; the last case in wild boar was detected in 2009. Surveillance is performed using the 59 sample size EU requirement, to be able to detect a 5% design prevalence and 95% confidence. However outbreaks have been occurring and the cost of this surveillance design is high. In order to improve the effectiveness of the surveillance system risk-based design surveillance were compared to the current design using simulation model.

Three attributes were identified as the most relevant to the evaluation of the effectiveness of this surveillance system:

- The sensitivity of the system, defined as the probability that disease will be detected if present at a certain level (prevalence) in the population,
- the timeliness, defined as the time between introduction and detection of infection,
- the acceptability of the hunters to enrol in the system (see Example 25).

Three different surveillance designs based on risk were tested and compared to the current surveillance design (as reference value). The surveillance designs were ranked according to the effectiveness outputs for each evaluation attributes from 1 (best) to 5 (least). We can see in the summary of the results below, that the ranking of the designs would be different according to the attribute considered.

| SURVEILLANCE DESIGNS | EVALUATION ATTRIBUTES | | |
|----------------------|-----------------------|------------|---------------|
| | Sensitivity | Timeliness | Acceptability |
| Reference | 1 | 3 | 2 |
| Design 1 | 3 | 1 | 1 |
| Design 2 | 2 | 4 | 3 |
| Design 3 | 4 | 5 | 4 |
| Design 4 | 1 | 2 | NA |

The results of this study suggested that a deeper insight in the overall power of a surveillance system could be gained when more than one effectiveness attribute were included in the evaluation process.

Best Practice Example 27. Evaluation of effectiveness of the CSF surveillance in wild boar in Germany

The assessment of each attribute will provide information on the effectiveness of the specific component or part of the system. Functional attributes (such as *acceptability*) have been shown to influence the effectiveness of the system. According to the evaluation question and the evaluation

method selected it might not always be possible to conclude on the evaluation outputs by looking at one single evaluation attribute alone. It is therefore recommended to consider all the attributes relevant to the specific object under evaluation when designing the evaluation plan and to assess them (see [Best practice example 27](#)).

Recently a generic method to assess the effectiveness of animal health surveillance systems has been developed (Grosbois et al. 2014). Under this method, effectiveness of a surveillance system is expressed in terms of discrepancy between the modalities and intensity of prevention and/or control measures that would be implemented, given a perfect knowledge of the true epidemiological status of a population, and the modalities and intensity of prevention and/or control measures that are likely to be actually implemented based on the analysis and interpretation of the data produced by a surveillance system. Therefore this method takes the functional limits of the system into consideration.

When evaluating the effectiveness of risk-based surveillance, it is needed to include the evaluation of the definition for the risk-based criteria.

ECONOMIC EVALUATION

As all surveillance activities incur costs, evaluation often also includes questions of costs or efficiency. However, if costs have not been documented, evaluation may be challenged by a lack of data. To assess whether surveillance investments have added an impact on disease prevention and control, benefits of surveillance may have to be considered. As the latter aspects are mostly captured qualitatively, a range of qualitative tools may be required (e.g. expert workshops, participatory approaches). Since economic evaluation is yet to be routinely considered in surveillance design an entire chapter (see Chapter 8) is dedicated to this element.

7.3.3 Level of evaluation

As was shown in Section 7.1 and Table 9, evaluation can be performed on a one-off basis but when it concerns evaluation of on-going surveillance system (components) it may be useful to repeat it over time.

The *scale* of evaluation relates to whether the evaluation is directed to a single (or few) of its components, or to the entire system (see Table 12 and Figure 18). The *degree of complexity* relates to whether a selection or all elements are under evaluation (see Table 12 and Figure 18). Evaluation *elements* can be: process (called functional in the figure), effectiveness, optimisation, and/or cost-benefit evaluation (see Section 7.3.2).

The combination of its scale and the degree of complexity determine the *level* of the evaluation, ranging from *selective* (evaluation of selected elements) to *comprehensive* (evaluation of all elements) (See Figure 19):

SELECTIVE EVALUATION will consider *the assessment of only one element* of the evaluation process, for instance effectiveness, or process/functional, or economic, and if performed at the component level this would be a simpler evaluation approach (Figure 18). This approach will be sufficient to inform the design or re-design process on the effectiveness of e.g. two or more alternative surveillance designs. In such case, the evaluation could be reduced to the assessment of a single selected *effectiveness attribute*, e.g. detection probability, to inform if a newly designed surveillance component, e.g. active surveillance in wildlife, is able to meet a target effectiveness and therewith to conclude on its relevance.

COMPREHENSIVE EVALUATION, on the other hand would imply *the assessment of all elements* of the evaluation process. Comprehensive evaluation performed at the system level would represent the most complex evaluation approach. Comprehensive evaluation could be performed at the system level *to assess the effectiveness of the system to generate its outputs* (effectiveness attributes, e.g. sensitivity or timeliness) and *the performance of the system process* (functional attributes, e.g. acceptability and engagement) and provide recommendations about how to improve the effectiveness and even efficiency of the system if economics is considered.

Evaluation of surveillance system (components) will provide guarantees to decision makers (internal or external) on the quality of the information generated by it and on the disease situation in the area under surveillance. These guarantees are critical elements for instance for trade regulations and access to international trading market (See also OIE and SPS) (See Figure 19).

Table 11. Information that will result from surveillance evaluation (Surveillance objective) according to evaluation level and elements

| SCALE EVALUATION | OF | EFFECTIVENESS | PROCESS | | OPTIMISATION | | COST-BENEFITS | |
|------------------|---|---------------|---|------------------|---|---------------|---|---------------|
| COMPONENT SCALE | To (re-)design | inform | To (re-)design | inform | To (re-)design | inform | To (re-)design | inform |
| | | | To stakeholder (relevance and sustainability) | ensure trust and | Resource allocation | | Resource allocation | Relevance |
| SYSTEM SCALE | To (re-)design | inform | To (re-)design | inform | To (re-)design | inform | To (re-)design | inform |
| | To information on quality of generated surveillance data and real disease situation | provide on of | To information on quality of generated surveillance data and real disease situation | provide on of | To information on quality of generated surveillance data and real disease situation | provide on of | To information on quality of generated surveillance data and real disease situation | provide on of |
| | To inform regulation authorities | trade | To inform regulation authorities | trade | To inform national decision makers for optimisation of resource allocation | | To inform the general public on the relevance of the surveillance system | |
| | | | To stakeholder trust | ensure | | | To inform national decision makers about options of different systems for resource allocation | |

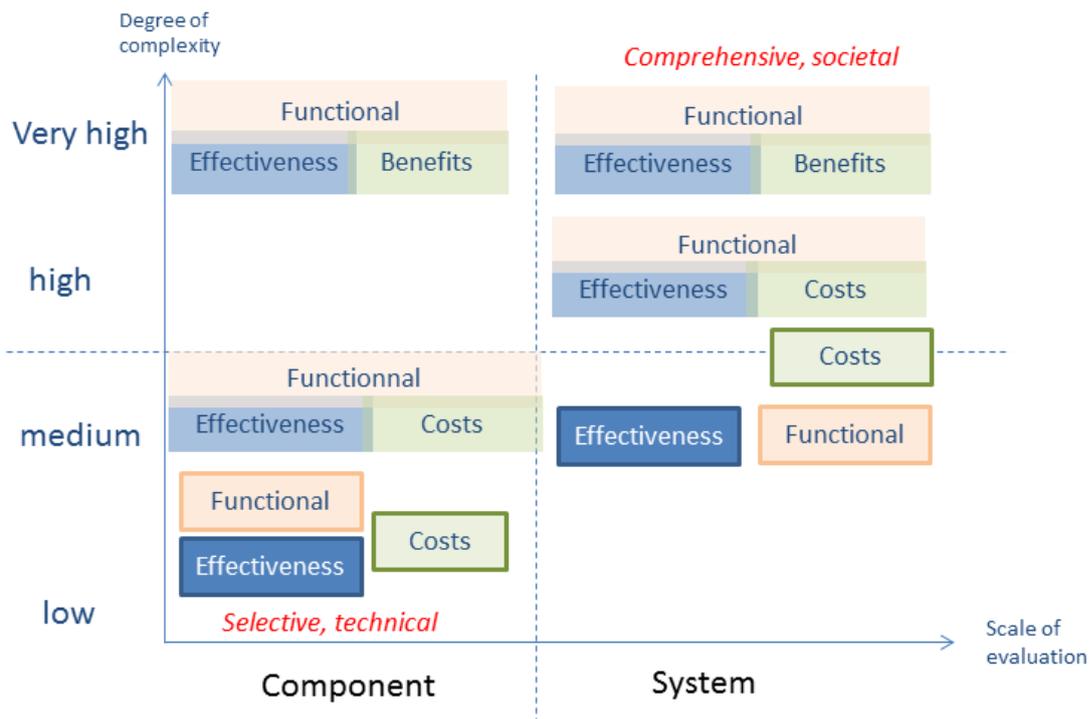


Figure 18. Degree of complexity and elements included in the different evaluation types (from selective to comprehensive)

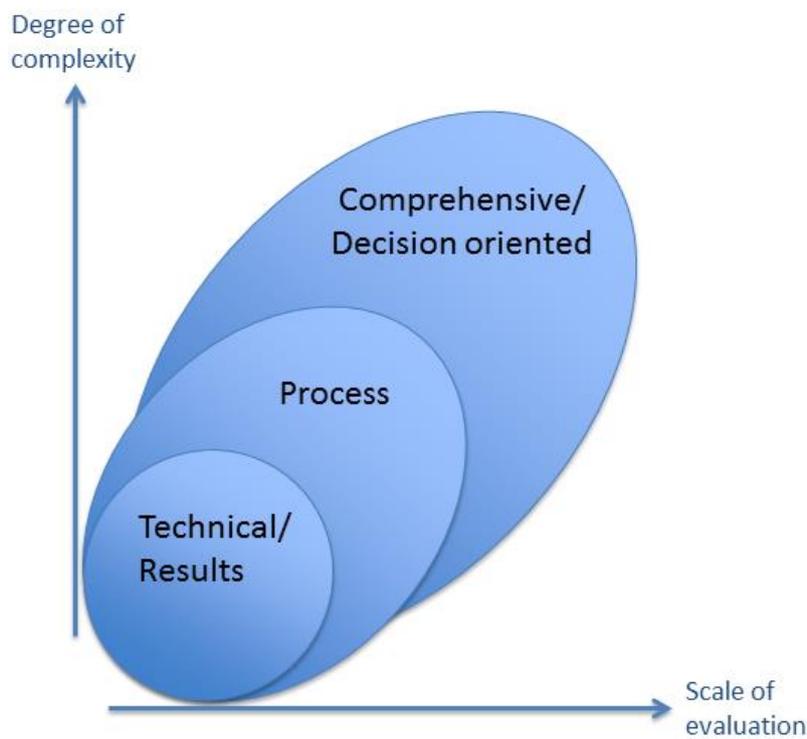


Figure 19. Level of evaluation: from technical assessment to the comprehensive context

7.4 LIMITATIONS BY CHOICE OF EVALUATION ELEMENT(S)

Choosing one or several evaluation elements without assessing another might have some limitations for the outcome. Some scenarios of element selection are considered here.

PROCESS WITHOUT EFFECTIVENESS EVALUATION - This evaluation will provide information on how to improve the system process, which in itself can have an impact on the effectiveness, but no information on the system effectiveness. The impact of the improvement will be difficult to assess if not combined with effectiveness evaluation. Applying process evaluation singularly will provide a base line analysis and descriptive view of the surveillance process.

EFFECTIVENESS EVALUATION WITHOUT PROCESS EVALUATION – This would provide limited recommendations as it will provide evidence based on the technical performance of the system and/or component but it will not provide information on *how* to improve the system (outside of the change in surveillance design), neither on the spill-over effect that a change in surveillance design will have on the rest of the surveillance process. Choosing only for effectiveness evaluation will be sufficient if intended for the selection of a surveillance protocol, for comparative testing of novel designs using simulation models or for system optimisation (assuming that if changes occurred this will not affect the rest of the system).

EFFECTIVENESS WITHOUT ECONOMIC EVALUATION – This will provide information neither on how to improve resource allocations nor on the relevance of the surveillance system for society.

ECONOMIC EVALUATION WITHOUT EFFECTIVENESS – As the information on the technical relationship is needed it is not possible to perform an economic evaluation of a surveillance system without also evaluation of its effectiveness.

COST ANALYSIS (WITHOUT PROCESS AND OR EFFECTIVENESS EVALUATION) – A cost analysis is meant for optimisation of the surveillance in meeting a technical target. This will neither require assessment of effectiveness nor of process performances. We only see this situation in surveillance very rarely. Usually, it is necessary to also evaluate the effectiveness to know that the technical target is met. And in order to be able to calculate the costs, the process needs to be illustrated or at least understood.

ECONOMIC EVALUATION encompasses the **ASSESSMENT OF COSTS**.

ECONOMIC EVALUATION WITHOUT PROCESS EVALUATION could limit the interpretation of the evaluation results in a similar way as for the evaluation of effectiveness on its own. It may not give information on *why*, but if the objective is to find out whether a planned strategy is beneficial or not, then the result will be fully justified for the purpose given and not limited.

PERFORMANCE MONITORING – Difficulties might be encountered to achieved consensus when developing performance indicators in a participatory manners (need a facilitator accustomed with participatory approaches). There is a risk to select only easy or very simple performance indicators, a risk to set a very low threshold value, a risk to select non-representative performance indicators.

7.5 TOOLBOX 7

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OIE surveillance manual (check list of evaluation attributes and detailed description)

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TOOLS

RISKSUR Surveillance Evaluation TOOL (EVA-Tool) :

The RISKSUR EVA-tool was developed to provide support and tools to enable users to define and formulated more precisely the evaluation questions and identify evaluation attributes. Besides a stepwise approach to guide the process towards a more targeted evaluation process and its documentation the tool provides support and background information.

How to obtain access: Once the tool becomes public the link will be provided in the EVA wiki (see below)

EVA wiki (explanations and help): Please request a code to become a member at <http://surveillance-evaluation.wikispaces.com>

Presentation of the EVA-tool (recorded webinar): via RISKSUR website <http://www.fp7-risksur.eu/node/225/> and the direct link to the webinar: <https://collab.switch.ch/p9j4ltjujk8/?launcher=false&fcsContent=true&pbMode=normal>

Training on how to use the Surveillance Evaluation Tool: <https://accelopment.adobeconnect.com/p5sty0i73kh/?launcher=false&fcsContent=true&pbMode=normal>

Presentation of the Surveillance Evaluation Tool (recorded): <http://www.fp7-risksur.eu/progress/surveillance-symposium-2015>

8 ECONOMIC EVALUATION

Economic evaluation of surveillance aims to provide evidence-based information on the “best” possible use of resources given their present values and the decision context, which could cover the individual, the sector and society. This process assumes that the goals are achieved in an efficient manner with least cost use of resources and programmes that are economically profitable i.e. their benefits outweigh their costs. Economic evaluation aligned with the policy cycle provides relevant information to take economically rational and efficient decisions.

Economic aspects are yet to be routinely considered in surveillance design and evaluation; there fore the RISKSUR consortium believes that this chapter will be useful to the reader. RISKSUR encourages the broader use of economic principles and hopes that the text will support readers in their application. More detailed explanations for support of this application can be found in [Annex B](#).

8.1 BENEFITS OF SURVEILLANCE

In a broad sense, surveillance can be considered as a scientific, factual tool that provides information for decisions regarding the implementation of interventions for disease control (Howe et al., 2013), which is expected to result in *disease control and therefore loss avoidance*, i.e. the dominant benefit. Another major benefit stems from the *facilitated trade* in situations where freedom from disease can be demonstrated. Surveillance to document freedom from disease in most cases constitutes a legislative requirement imposed to enable trade, both in the intra-community market and with third countries. The ability of a country to demonstrate freedom from disease or infection facilitates trade in line with the Sanitary and Phytosanitary Measures (SPS agreement, WTO, 1995), as the likelihood of importation of the disease is zero. Further surveillance benefits include *better information, improved knowledge, reputation, employment, or feelings of knowing to do the right thing*. (See also Chapter 7)

8.1.1 Disease loss avoidance

Together, *surveillance and intervention* achieve disease mitigation (disease control) and therefore **LOSS AVOIDANCE**, which constitutes the desired benefit (See also Section 4.2). In this three variable relationship, surveillance and intervention can be economic complements or substitutes (Howe et al., 2013). Surveillance and intervention resources *as complements* means that they always go together in a given ratio and can be considered to be one input, for example as seen in a testing (surveillance) and culling (intervention) strategy. Surveillance and intervention *as substitutes* means that using more of one input will allow the use of fewer resources for the other to achieve the same loss avoidance. The most prominent example is early warning surveillance that aims to enable early response and containment of disease. Detecting a disease early through surveillance enables intervening at a point when the losses due to animal disease and disease spread are still limited, and resources required to tackle cases are lower than later in an outbreak.

When surveillance and intervention are *substitutes*, for optimal efficiency, the *combined* cost of surveillance and intervention should be minimised for a given disease mitigation objective (e.g. “reduce prevalence of disease x in population y by 10%”, “eradicate disease from population z” - technical measures of disease occurrence). Any given level of value losses avoided may be obtained from different combinations of surveillance and intervention effort.

Figure 20 summarises the key principle: curves A1 and A2 represent two hypothetical levels of loss avoidance, which can be achieved by multiple combinations of surveillance and intervention. They illustrate the possibility of substitution between surveillance and intervention for two out of

potentially very many feasible levels of avoided losses. The loss avoidance in curve A2 can be achieved by either doing a lot of surveillance and limited intervention (S^* and I^*) or limited surveillance and a lot of intervention (S° and I°).

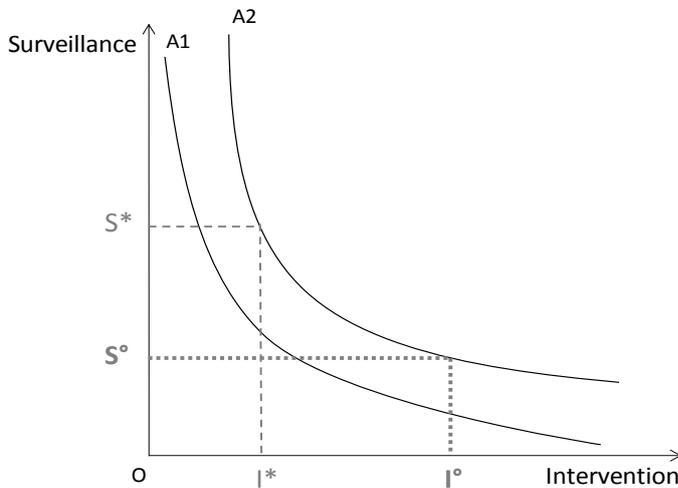


Figure 20. The curves A1 and A2 describe two defined levels of loss avoidance (where $A1 < A2$) that can be achieved by varying levels of surveillance (S) and intervention (I). (From Haesler et al., 2013)

Figure 21 illustrates that when including budget lines (i.e. lines that represent all combinations of surveillance and intervention that, when added up, have the same total amount of mitigation expenditures), the least-cost combinations of surveillance and intervention for the highest possible level of loss avoidance can be identified. The least-cost combination of surveillance and intervention use for this budget line is where the line touches curve A2 (marked with a dot). Other combinations along the budget line are possible as well, but will yield lower values of loss avoidance, for instance at the level of curve A1 (marked with stars in Figure 21). (See [Annex B](#) for additional explanation).

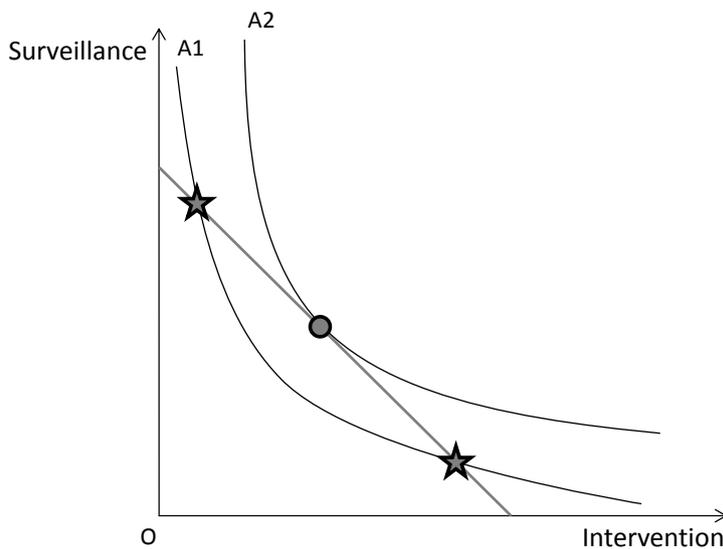


Figure 21. A higher level of loss avoidance (curve A2) can be achieved with the ideal combination of resource use (where the budget line touches the loss avoidance curve, marked with a dot)

8.1.2 The value of information

One major purpose of surveillance systems is to provide information to guide the action of policy makers. Information can be regarded as a commodity that has a certain value to society. Even though most people would agree that information may be valuable, there is no common, standardised system available to view, define, value and measure information. Such intangible benefits are generated when surveillance is used to, for example, inform risk assessments, identify gaps on surveillance systems, shape research agendas, or aid in outbreak investigation exercises, all of which contribute to intellectual capital, to the generation of social capital, and pertain to the value of peace of mind (Babo Martins et al, under review). The expenditures for gathering, interpreting, communicating and managing information should not exceed the benefit that results from having the information. If surveillance is implemented without measuring a tangible benefit, the expenditures made for surveillance can be interpreted as the minimum implicit value of non-monetary benefits stemming from information that must accrue for the surveillance expenditures to be justified.

In the “*value of information*” (VOI) approach the benefit of (additional) information in a specific decision-making context is evaluated (Laxminarayan and Macauley, 2012). It is based on decision-tree analysis that compares different states of action that may be taken depending on the amount of perfect or imperfect information available. Each possible action produces a certain amount of costs, depending on the probability of occurrence of a threat, e.g. disease. This framework allows policy makers to identify areas in which the combinations of probabilities and costs lead to a high VOI. Applications in the field of surveillance have been reported (e.g. Convertino et al. 2014; De Gourville et al. 2006), but remain sparse.

Similarly, a *novel approach for assessing the performance of a surveillance system and the probability of errors* (Grosbois et al., 2015) allows comparing the “decisions that would be made if the true state of a population was known” with the “decisions that are actually made upon the analysis and interpretation of surveillance data” and estimate the probability of Type I (interventions are unnecessarily activated) and Type II errors (interventions are not implemented even though they would be required because of true state of the population). The calculation of the economic consequences of these errors can be estimated, multiplied by the probabilities of these errors and compared directly to the investment needed to reduce the probability of this error.

8.1.3 Other benefits

FEELINGS - Benefits stemming from *feelings* such as *safety, contentment or “peace of mind”* are difficult to value. A popular approach is *Willingness-To-Pay (WTP)* or *contingent valuation (CV)*. This approach has been widely used to assess the value of ecological systems, health attributes and safe food. It was developed to assess non-market environmental benefit (e.g. clean water and air), but has increasingly been used in health economics. It consists of estimating the value that individuals attribute to a good or service, i.e. ask them what they are willing to pay, sacrifice or exchange for a good. The approach is based on the assumption that the maximum amount an individual is willing to pay for a commodity reflects the value it has for this person. The main criticism of the WTP is that it does not give reliable valuations. Since the choices are more hypothetical than real, there is the possibility that what people say that they are willing to pay and what they would actually pay may be different. Another drawback is that non-users of a good or service might find it difficult to attribute a value to it because their knowledge of it is very limited. The approach has been used to value the expected benefits from improvements in food safety and animal welfare, but has not found much application in animal health surveillance. For an example in animal health surveillance see Best practice example 28 by Delabougliše et al. 2015.

TRADE - The potential benefit of being able to *trade* is so large, that surveillance costs are commonly perceived to be justified and the analysis focuses on *achieving a minimum target effectiveness at least cost* (see next section).

28

The value that individual actors place in animal health information can be understood in two different ways:

- 1) The benefit individuals attribute to the *reception of information* on outbreak occurrence of a specific disease (the value may depend on several factors, including distance from a trade connection with the identified outbreak location).
- 2) The *benefits and costs* individuals attribute to the *reporting of information* to veterinary services. This value depends on anticipated consequences of reporting. These consequences can be perceived as negative or positive.

A pilot case study in North of Vietnam illustrates how the value of animal health information can be assessed using economic tools. The general objective was to evaluate the perceived value of information produced by the passive highly pathogenic avian influenza (HPAI) surveillance system in domestic poultry. This surveillance system has been in place since the first HPAI occurrence in 2003 and is based on compulsory reporting of HPAI suspicions to veterinary authorities.

1) To evaluate *the benefits private actors attribute to the reception of information provided* by the surveillance system the qualitative identification of the nature of such benefits, through semi-structured interviews was crucial. Figure 22 illustrates the two natures of these benefits: avoidance of production losses due to the disease, and anticipation of market impacts of the disease.

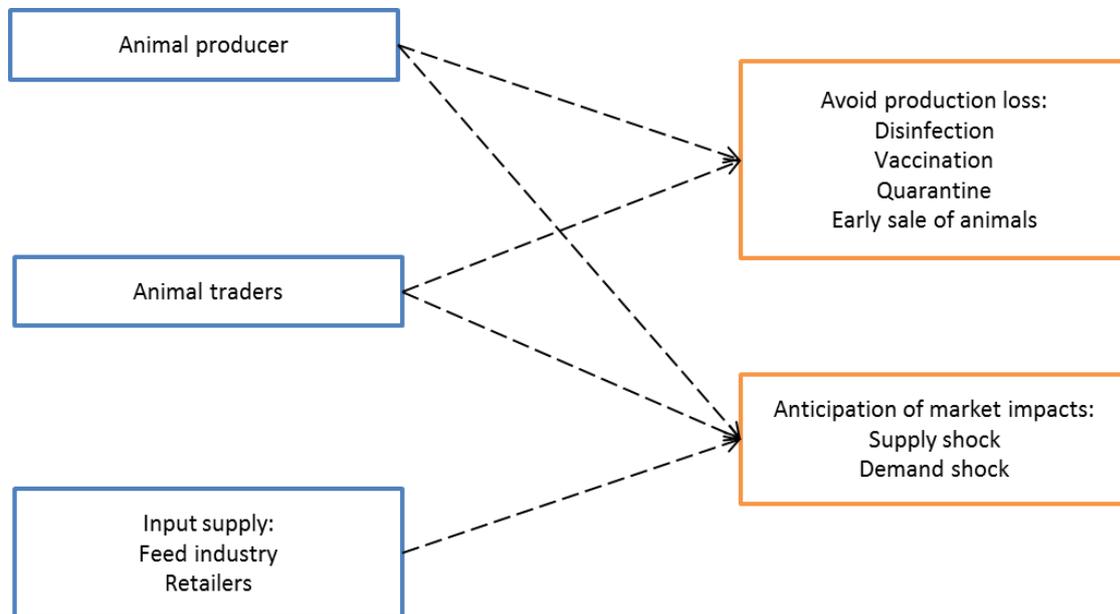


Figure 22. Perceived benefits attributed to the reception of information related to HPAI suspicions, from the point of view of different categories of private actors

A way to quantify such benefits is through direct financial estimation by interviewed actors. Therefore, a protocol adapted from contingent valuation was built and tested with 21 chicken broiler producers. It was based on the hypothetical scenario of a company collecting and selling information on outbreaks. It had to be made clear that the only service offered by the company to farmers was the delivrance of information.

28

(CONTINUED)

Figure 23 summarises the order of questions used to quantify benefits perceived by the interviewed farmers. They were first asked to estimate the economic losses they could avoid thanks to information on disease outbreaks for each broiler cycle. Then they were asked how much they would pay during each broiler cycle to receive the abovementioned hypothetical private service.

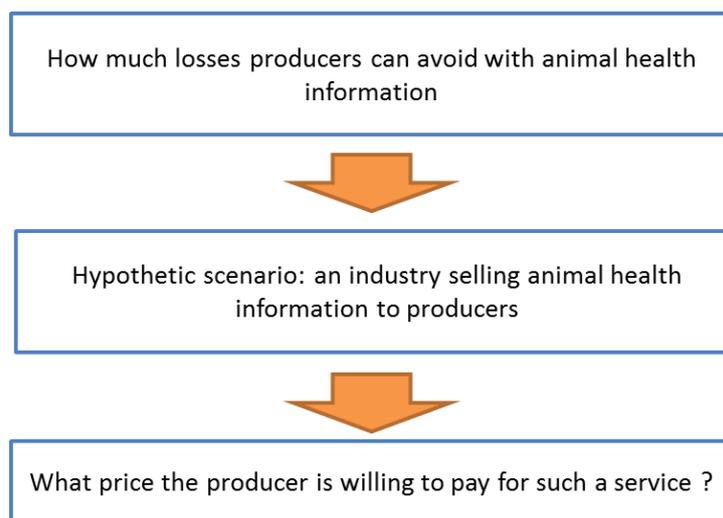


Figure 23. The different steps of the quantification tool based on contingent valuation aimed at valuating the benefit derived from the reception of information on disease outbreaks

The estimated benefit ranged from 100 Vietnam dollar (VND) (0.005 USD)/chicken/cycle to 1000 VND (0.05 USD)/chicken/cycle. The median value was 830 VND (0.04 USD)/chicken/cycle which equals approximately 1% of chicken market price.

2) The other objective was *to quantify costs and benefits attributed to information reporting* to veterinary services. A preliminary qualitative data collection phase was indispensable to identify the negative and positive consequences expected from HPAI suspicion reporting.

There were financial and non financial factors influencing the willingness of farmers to report. Examples of *financial factors* were the indemnities provided by the state to compensate the culling of the infected flock and the foregone possibility to sell the infected broiler flock to itinerant traders. Examples of *non financial factors* were the expectation of positive impacts of reporting on disease control and environmental cleanliness, but also the drop of broiler chicken market price, which negatively impacted other farmers.

Such factors could not be directly quantified. Therefore, a specific tool was built, based on conjoint analysis. It consisted in asking interviewed farmers to estimate the probability that they report HPAI suspicions in their farm to veterinary authorities, using proportional piling, and under the assumption of different scenarios with variable attributes: variable amount of financial benefit from reporting and variable consequences of reporting (in terms of market impact and implemented control measures). The quantification (in monetary units) of each scenario attribute on farmers' decision was then done using multinomial logistic regression.

The tool was developed in 6 interviews and tested on 17 broiler chicken producers. 11 tests produced interpretable results. The proposed method is therefore effective, though it is complex to implement and requires lengthy interviews (2 hours in average). Convincing interviewees to think through different hypothetic scenarios might, in some case, be challenging and interviewers must be trained in using the tool before applying it.

Best Practice Example 28. Evaluation of the value of animal health information

8.2 COMMON ECONOMIC EVALUATION TECHNIQUES

Given that economic evaluation compares the resources requested for doing an action to the consequences or outcomes of that action, several principal types of full economic evaluation, where both inputs and consequences are valued, can be used to evaluate surveillance from an economic point of view (See Table 13). Partial evaluation only offers one side of the picture, i.e. either the “value” or “the money”. The three economic evaluation techniques for surveillance most commonly used in animal health, namely **COST-BENEFIT ANALYSIS (CBA)**, **COST-EFFECTIVENESS ANALYSIS (CEA)**, and **LEAST-COST ANALYSIS** are described briefly below and in more detail in [Annex B](#). Their common feature is that they are used to compare distinct options (at least two) to identify whether an option generates a net benefit or if an option is preferable to another one. Both CEA and CBA look at *marginal* changes. In CEA there are marginal costs compared to a marginal change in a desired outcome(s). The CBA places a value on these outcomes and makes them benefit streams.

Other techniques with large potential for application in animal health surveillance are:

- **COST-UTILITY ANALYSIS** - Costs are compared to utilities, in particular quantity and quality of life (but can include other ordinal notions describing an agent’s preference) Recommended reading: (Drummond, 1997);
- **OPTIMISATION ANALYSIS** - The net benefit for society as a whole can be maximised by looking at a continuum of combinations and identifying the optimal combination of *surveillance*, *intervention* and *loss avoidance* that maximizes social net benefits, see for example Vergne et al. (forthcoming).

Table 12. Comparison of full and partial economic evaluation techniques. Modified based on Drummond, 1997

| | Are both costs and consequences of the alternatives determined? | | | |
|--|---|----------------------------|---------------------|--|
| | NO | NO | YES | |
| | | EXAMINES ONLY CONSEQUENCES | EXAMINES ONLY COSTS | |
| Is there a comparison of two or more alternatives? | | Outcome description | Cost description | Cost-outcome description |
| | YES | Effectiveness assessment | Cost assessment | Cost-effectiveness analysis Cost-benefit analysis Least-cost analysis ¹ (Cost-utility analysis) (Optimisation analysis) |

¹ Listed in this cell, because in most surveillance systems the outcome needs to be measured as well.

8.2.1 Cost Benefit Analysis

In a cost benefit analysis (CBA), it is important to quantify both the costs and benefits (avoided losses) of a mitigation programme *in monetary terms*. Social CBA refers to the impact assessment of a programme on societal level, these impacts may be economic, environmental, biological and medical (Rushton et al., 1999) and include externalities (e.g. shadow prices).

In animal health, social CBA is rarely used, the more popular method is *financial CBA* where all costs and benefits are valued based on market price and subsidies are seen as an income stream. These CBA often relate to infectious disease (epidemic and endemic) and its control (i.e. avoidance of disease losses); only few publications are available that explicitly assess the value of surveillance. Losses that are caused by disease and can be avoided with surveillance and intervention are for example mortality, abortions, reduced milk yield or reduced egg production. Moreover, expenditures for interventions are extra resources used as a consequence of the disease (e.g. vaccines, veterinary services, drugs) that can be avoided and are therefore part of the benefit. See Best practice example 29 for the application of CBA in animal health surveillance.

The key steps in a CBA are summarised here, for further details and explanation please see [Annex B](#):

1. Identify surveillance options to be compared (note that an option can be the “no surveillance” scenario = the baseline)
2. For each programme, identify the steps requiring financial inputs (costs of surveillance and of intervention)
3. Identify all the potential losses incurred by the disease for all options
4. Measure and value the costs and the benefits (losses avoided) in the same monetary unit
5. Compare the costs and benefits between the different programme options

29

This example of a CBA in its broader sense takes account of both the benefits and costs of a strategy in the Netherlands¹. The group *applied epidemiological and financial models to simulate* classical swine fever epidemics and the impact of five existing surveillance programme components on the disease dynamics.

The *effectiveness of surveillance* was measured by the *time from introduction of the virus to its detection*, which determined the number of infected herds at the time of detection and thus *the epidemic costs*.

The *annual costs per surveillance programme* and *outbreak related costs* accruing from culling of detected herds, contact tracing, establishment of protection and surveillance zones and preventive culling were estimated.

It was reported that the surveillance programme implemented averted very expensive outbreaks with a high probability. It was stated that the precise value of the benefit of surveillance depends on the frequency of entry of the virus into the Netherlands; predictions of such an event vary between once every two years to once every 18 years.

¹ Klinkenberg, D., Nielen, M., Mourits, M.C., de Jong, M.C., 2005. The effectiveness of classical swine fever surveillance programmes in The Netherlands. *Prev. Vet. Med.* 67, 19-37.

Best Practice Example 29. Cost benefit analysis of classical swine fever surveillance in the Netherlands

8.2.2 Cost effectiveness analysis

Contrary to CBA where the benefit is expressed in monetary terms, cost effectiveness analysis (CEA) aims to assess the outcome of a programme *in non-monetary terms* in relation to its costs. In human health economics the outcome often refers to the avoidance of illness or death, while in animal health other technical measures such as *probability of the detection of cases of disease* or *number of abortions avoided*.

Unlike in health economics, where attempts have been made to harmonise CEA methodologies and encourage comparability of studies (Murray, Evans, Acharya, & Baltussen, 2000), there are no specific guidelines available yet for its application in animal health. Whenever possible, *the measure of effectiveness should reflect a final outcome* and not an intermediate outcome, even though the use of an intermediate measure is valid if it has a value on its own (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005). If a final outcome is considered such as “the number of livestock dying” or a “change in milk yield”, the value is already monetized, as animals have a price as do their products and hence the result of a CEA is directly interpretable (e.g. “cost per cow-death avoided”).

However, given resource and technical constraints, there is *a demand in the surveillance community to include intermediate outcomes* instead of final outcomes in CEA. For instance, an effectiveness measure such as timeliness may be considered to be a proxy for the final outcome or benefit, such as loss avoidance and reduced intervention expenditures due to earlier outbreak detection (which would be measured explicitly in a CBA). But CEA of surveillance can inform resource allocation meaningfully only if the effectiveness measure has an *interpretable value*. For example, the value of timeliness may have been established in studies of past outbreaks to know that each day of earlier detection of a highly pathogenic avian influenza (HPAI) outbreak resulted in the avoidance of losses worth £100,000 (136.000 euro). In such a case, a cost-effectiveness ratio of a surveillance system to early detect HPAI expressed as “costs/days of earlier detection” can be easily interpreted. However, without this information, effectiveness measures like “time of introduction of disease until detection” or “the probability of detecting an outbreak” are not informative in a CEA.

Therefore, before conducting a CEA, it is necessary to think carefully about how the findings can be interpreted and whether the value of an effectiveness measure can be compared to the additional costs.

There are *three types of cost-effectiveness ratios* corresponding to different uses; 1) average cost-effectiveness ratio (ACER), 2) incremental cost-effectiveness ratio (ICER), marginal cost-effectiveness ratio (MCER). Those are treated in [Annex B](#).

8.2.3 Least-cost analysis

In least cost analysis (LCA), the cost is the dominant determining factor in a choice between different options, because the outcome or the value of the outcome is the same for each option. The valid application of the method depends on establishing that the cost is indeed the determining factor and that the effectiveness is the same for the surveillance options to be compared.

Least-cost analysis in surveillance can be categorised broadly into two groups:

TARGET DEFINED - Comparison of different surveillance options that achieve a defined target in terms of effectiveness (e.g. demonstrate with a confidence of 95% that a country is free from a disease or achieve a sensitivity of detection of 80%). For this economic evaluation, it is necessary to first establish the *equal effectiveness* using relevant methods. Next, the *costs of all equal*

options can be calculated and the options be ranked according to costs. By adopting the least-cost of equal surveillance options, the highest net benefit can be achieved.

PROTOCOL DEFINED - Where the surveillance protocol is a given, by for example legislation (e.g. definition of the types and number of farms and samples, laboratory testing and analysis procedures are described), it can be expected that the surveillance component achieves the desired effectiveness. Different surveillance options to be compared then can only look at changes in the implementation of the surveillance (e.g. use cheaper test tubes from a different manufacturer, use synergies between programmes) and select the option that complies with the given requirements at minimum cost.

8.3 QUANTIFYING INPUTS AND OUTCOMES (COSTS AND BENEFITS)

The important concept of *loss avoidance* is illustrated here with an example of early warning surveillance, where detecting disease early is expected to lead to a more rapid response (e.g. implementation of outbreak control measures) relative to the time of occurrence of the index case. Earlier in the outbreak, the losses already generated by the disease are smaller than at a later time. Consequently, less spread means that the costs of intervention measures required are smaller than later in the outbreak with more animals and/or holdings being affected (Figure 24).

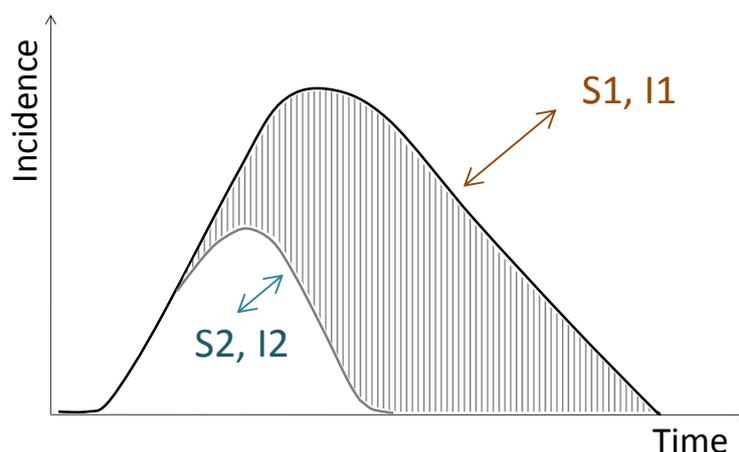


Figure 24. Comparison of two surveillance options (S1 and S2) and their associated interventions (I1 and I2) in a situation where S2 leads to earlier detection of disease and I2 to effective disease control. The hatched area represents the losses avoided with the more effective combination of S2 and I2

TO ESTIMATE THE VALUE OF LOSSES AVOIDED, it is necessary to identify the effects in the animals or holdings affected as well as the effect of potential externalities. The losses can then be estimated by multiplying the number of animals of a certain type or species (e.g. dairy cows) suffering from a disease impact (e.g. reduction in milk yield) by the lost physical production coefficient (e.g. rate of reduced milk yield in dairy cows) and the price coefficient related to the disease impact (e.g. production price per litre cow milk). All disease effects need to be “translated” from a technical perspective into a value perspective in this way and summed up. The resulting difference in losses between two strategies is the benefit.

Because economic evaluation of surveillance is mostly concerned with *marginal analysis*, i.e. we want to know the consequences of a change and are only looking at small changes instead of assessing the whole system, the analyst needs to *differentiate between fixed and variables costs*. *Fixed expenses or costs* are those that do not fluctuate with changes in the surveillance level, e.g. rent, insurance, payment on loans, etc. In other words, these costs need to be covered independent

of the change in surveillance. *Variable costs* change dependent on the level of surveillance. In most marginal analyses only the variable costs will need to be considered, but it is important to acknowledge that the fixed costs of a system are critical in ensuring a minimal capacity of the system.

When CALCULATING THE COSTS BOTH FOR SURVEILLANCE AND INTERVENTION, it is recommended to first define all the resource requirements in terms of labour, operations, and expenses for surveillance and intervention activities by the following steps:

| SURVEILLANCE | INTERVENTIONS |
|--|--|
| Planning | Planning |
| Preparation | Preparation |
| Sampling | Implementation |
| Laboratory testing | |
| Data management | Data management |
| Data analysis | Data analysis |
| Communication | Communication |
| Supervision | Supervision |
| Revision and adaptation of current programme | Revision and adaptation of current programme |

For each the relevant physical inputs (e.g. working hours per professional involved) then need to be multiplied by relevant price coefficients (e.g. the wage rate for the respective professional level) and added up to estimate the total costs.

If the analysis spans several years in prospective scenarios, the future costs and benefits need to be translated into present values by multiplying the costs or benefits by the *discount factor* $1/(1+r)^t$, where r is the discount rate and t the time in years.

8.4 TOOLBOX 8

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TOOLS

RISKSUR Surveillance Evaluation TOOL (EVA-Tool) :

The RISKSUR EVA-tool was developed to provide support and tools to enable users to define and formulated more precisely the evaluation questions and identify evaluation attributes. Besides a stepwise approach to guide the process towards a more targeted evaluation process and its documentation the tool provides support and background information.

How to obtain access: Once the tool becomes public the link will be provided in the EVA wiki (see below).

EVA wiki (explanations and help): Please request a code to become a member at
<http://surveillance-evaluation.wikispaces.com>

Presentation of the EVA-tool (recorded webinar): via RISKSUR website <http://www.fp7-risksur.eu/node/225/> and the direct link to the webinar:
<https://collab.switch.ch/p9j4ltjuk8/?launcher=false&fcsContent=true&pbMode=normal>

Training how to use Surveillance Evaluation Tool:
<https://accelopment.adobeconnect.com/p5sty0i73kh/?launcher=false&fcsContent=true&pbMode=normal>

Presentation of the Surveillance Evaluation Tool (recorded):
<http://www.fp7-risksur.eu/progress/surveillance-symposium-2015>

Evaluation should lead to a judgment of the system and/or recommendations to strengthen it (see Chapters 2 and 7). Hence, the evaluation exercise is completed by a deep analysis of the results that would potentially lead to the identification of improvement measures. The evaluators can already have included a judgement based on the results in the evaluation report, or leave the judgement to a larger group. The evaluation team members and other members (e.g. decision makers, policy officers, risk assessment bodies, and more) will critically reflect on the completed work and look for opportunities to improve the surveillance efforts and effects. This can be done in a meeting with all those involved to examine how to apply the results by reviewing the data, identifying key areas for improvement, and brainstorming and coming to consensus on how to address issues that have been raised. Some key reflection questions that might be considered:

WHAT ARE WE SEEING? - E.g., amount and kind of activities implemented; results shown – efficiency, efficacy of the systems, trends;

WHAT DOES IT MEAN? - E.g., how to interpret the results and translate them in concrete research and/or policy actions;

WHAT ARE THE IMPLICATIONS FOR IMPROVEMENT? - E.g., do the results suggest that the intervention should be sustained, altered, discontinued; what changes are suggested.

Additional targeted questions should then be added depending on the objective of the surveillance and specific evaluation questions (see Chapters 7 and 8).

Consider holding a *meeting or brief retreat* where the evaluation results can be presented through graphs and charts, and key questions can be discussed. Participants to this meeting should include the evaluators and the responsible bodies of the surveillance programme(s) under scrutiny but not only. The meeting shall also include external experts and policy officers that could bring an external view of the results of the evaluation. The best plan here is to involve a number of stakeholders, depending to some extent on who has been involved in the planning and evaluation of the effort. Such a meeting might benefit from an experienced facilitator to keep the process moving toward consensus for specific recommendations on how to improve.

Refining the evaluation activities is the primary purpose of monitoring and evaluation (See Chapters 7 and 8). Performance monitoring and feedback from stakeholders, or anybody actively involved in the activities, allow for making adjustments throughout the period that the surveillance system (component) is running. The judgement deriving from the evaluation directed at the different elements and levels can lead to several reasons for adjustments. Without treating each evaluation question and its possible results in detail, at a larger scale the approach could be the following.

If it is assessed that the evaluation efforts were *not effective or efficient*, two main options are possible: apply another approach or use the evaluation assessment to guide towards a more effective and/or efficient intervention. Evaluation elements, level, and the specific evaluation questions will guide the decision towards adjustments. Each aspect of the evaluation builds on what comes before. In order to obtain the desired impacts, the surveillance has to be implemented properly, and that's a matter of process. If the process didn't go properly, then the programme that was planned for has not been corrected conducted. If the impacts that were hoped for have not been observed, it may be due to the fact that what was planned was not what was done, and the first adjustments should be to the process, to ensure that the intervention is implemented as intended. Similarly, to get the intended outcomes, the programme has to have an impact on the appropriate risks and protective factors. If the programme had the envisioned impacts, but not the

outcomes, then adjustments need to take place at the impact level, perhaps in the risk and protective factors and/or conditions that influence outcomes.

But also if the evaluation efforts *were effective*, there might be reasons to make adjustments to improve for instance efficiency and reduce the costs. The judgement after analysing the evaluation results could be that, depending on the objectives, even though the surveillance has been serving its objectives well, 1) adjustments could even improve this output, or 2) as a result there might be a shift in prioritisation, or 3) meanwhile another approach might have been identified that could lead to even decreased resources for the same or higher outcome.

If the surveillance system (component) had *the expected impact but no outcomes*, perhaps the behaviours or factors to target have been wrongly selected, leading to a need to rethink the problem analysis and related intervention. Other plausible explanations are for instance that the surveillance wasn't in place long enough, the effects are delayed, and the measures are insensitive to what is being achieved. The next step here is to understand how well the project was planned, prepared for, and implemented. If the reasoning and assumptions behind the planning were accurate, and the surveillance activities implemented were based on these, the impacts aimed for should be obtained, and that impact should lead to the desired outcomes. If the programme didn't go as planned, that could be due to the lack of outcomes.

IN CONCLUSION, the real value of evaluation lies in its ability to help identifying and correct problems – as well as to celebrate progress. Evaluation can pinpoint the strengths of the surveillance, and help to protect and enhance those strengths and make them even stronger under cost-optimisation approaches. By examining the three elements of an intervention – process, impact, and outcomes – any evaluation can assess whether what was planned was what was really implemented; whether what was done influenced behaviours and factors intended to lever; and whether the changes in those factors led to the intended outcomes. That knowledge can show what might need change to improve the system.

10 CONCLUSION

Principles and methods used in surveillance are constantly evolving. With this document, we summarise the state of good practice at the time when the RISKSUR project finished (October 2015). We recognise that the document should ideally be updated in a few years. And even now there are some gaps, some of a technical nature and some are more related to the transfer of knowledge into practice.

Novel data collection methods result in the need for new analytical approaches. This is the case, for example, in syndromic surveillance, and with the new opportunities that Big Data and the Internet of Things will provide (Pfeiffer and Stevens 2015)². The outputs generated by the more demanding analyses, likely to use machine learning as well as statistical methods, need to be presented such that decision makers can interpret them, while appreciating the associated uncertainties. Furthermore, the required technical competencies will need to be developed amongst staff, and it will be challenging to keep appropriately qualified staff due to the high demand for their skills in various types of industry. Also, the competency of technical staff needs to be substantial to apply novel surveillance methods that require knowledge from a range of fields including epidemiology, statistics, computer science, but also the social sciences, most notably economics. Data availability and quality will remain an issue, if not become even more important due to the need to integrate a variety of different data sources.

An important task will be establishing effective communication between policy makers and those designing and implementing surveillance systems and producing surveillance outputs. Policy makers usually do not have, and probably do not need to, the detailed technical knowledge about the design methodologies, but they have a particular responsibility to take acceptability of surveillance across diverse stakeholders into account, which in turn will influence effectiveness. Also, documentation of surveillance protocols is often incomplete so that transparent and objective comparisons between different designs are difficult for stakeholders. This is particularly relevant for risk-based surveillance, which should perform better in terms of effectiveness, but this can only be shown if transparent and widely accepted procedures are used to generate suitable outputs. The availability of such information will be essential for communicating with potential trading partners who will otherwise lack confidence in the outputs generated by the surveillance system.

Surveillance practice is also driven by standards set in countries' legislation and international standards. However, such standards may not be flexible enough to allow for the latest, perhaps more effective or efficient methods to be applied. Knowledge transfer and uptake is therefore essential to improve surveillance practice beyond the academic sphere. RISKSUR has made an effort in using a range of channels to bridge the gap between theoretical and practical aspects of surveillance. Dialogue between academia and the wider surveillance profession is essential and needs to be maintained. However, activities that are not clearly within the remit of either sector are often neglected and eventually forgotten.

Projects such as RISKSUR run for a defined time period and then stop. Researchers move on to other funding sources and other topics. However, the application of surveillance continues to be highly relevant. We hope that the foundations provided by RISKSUR will help create a sustained focal point for good practice in surveillance. The current document should be seen as a starting point, and it needs to be updated regularly to reflect future developments. Freely accessible resources such as the RISKSUR surveillance glossary are also available to the surveillance community to use and updating, now and in the future.

² Pfeiffer, D.U. and Stevens, K.B. 2015: Spatial and temporal epidemiological analysis in the Big Data era. *Prev Vet Med.* <http://dx.doi.org/10.1016/j.prevetmed.2015.05.012>.

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RISKSUR WEBLINKS

Best Practice Workshop: The Hague 2014 (Deliverable 7.31), <http://www.fp7-risksur.eu/progress/public-deliverables>

Best Practice Workshop (Annex) (Deliverable 7.31), Barbara Häslér, The surveillance landscape in Europe, The Hague, The Netherlands, 30 September 2014, <http://www.fp7-risksur.eu/progress/public-deliverables>

Best Practice Workshop (Annex) (Deliverable 7.31), Review of surveillance guidelines, <http://www.fp7-risksur.eu/progress/public-deliverables>

EVA tool: <http://www.fp7-risksur.eu/news-events/surveillance-surgery-n°6-risksur-surveillance-evaluation-framework>

Glossary: <http://www.fp7-risksur.eu/terminology/glossary>

LinkedIn Group: <https://www.linkedin.com/grp/home?gid=5029768>

Mapping (Deliverable 1.1), <http://www.fp7-risksur.eu/progress/public-deliverables>

Surveillance design framework: <http://www.fp7-risksur.eu/news-events/risksur-surveillance-design-framework-available>

Surveillance design framework wikispaces: <https://surveillance-design-framework.wikispaces.com>

Terminology: <http://www.fp7-risksur.eu/terminology>

Terminology, Frequently Asked Questions: <http://www.fp7-risksur.eu/terminology/faq>

Webinars: <http://www.fp7-risksur.eu/progress/training-and-webinars>

ADDITIONAL WEBLINKS

ASFORCE (EU FP7 project, online), <http://asforce.org/training> including an online course: <http://asforce.org/course>

AUSVET Epitools, <http://epitools.ausvet.com.au/content.php?page=home>

CDC (Centers for Disease prevention and control) Healthcommunication - <http://www.cdc.gov/healthcommunication/risks/index.html>

EU-FMD (EU project) E-learning (online), <https://eufmd.rvc.ac.uk>

FAO (Food and Agriculture Organization of the United Nations) E-learning (online), <http://www.fao.org/elearning/#/elc/en/home>

FAO-manual (see Cameron et al., 2014), <http://www.fao.org/3/a-i4205e.pdf>

ICAHS terminology report (See Hoinville et al., 2013), http://www.fp7-risksur.eu/sites/fp7-risksur.eu/files/partner_logos/icahs-workshop-2011_surveillance_terminology_report_V1.2.pdf

IFAH (International Federation for Animal Health Europe), Brussels, Belgium <http://www.ifaheurope.org>

Sweden digital reports, <http://www.sva.se/om-sva/publikationer/sjukdomsovervakning/surveillance-of-zoonotic--other-animal-disease-agents-in-sweden1>

Triple S project (EU FP7 project, online): Syndromic Surveillance in Europe: <http://www.syndromicsurveillance.eu>

UK government publication on control strategy, <https://www.gov.uk/government/publications/notifiable-avian-disease-control-strategy-for-great-britain>

World Trade Organization (WTO), SPS agreement, 1995 (online), https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

Textbox 6. Confidence level explained for Best practice examples 10 to 13

Confidence level: In survey sampling, different samples can be randomly selected from the same population; and each sample can often produce a different *confidence interval*. Some confidence intervals include the true population parameter; others do not.

A confidence level refers to the percentage of all possible samples that can be expected to include the true population parameter. For example, suppose all possible samples were selected from the same population, and a confidence interval were computed for each sample. A 95% confidence level implies that 95% of the confidence intervals would include the true population parameter.

Confidence interval: Statisticians use a confidence interval to express the degree of uncertainty associated with a sample statistic. A confidence interval is an interval estimate combined with a probability statement.

DEMONSTRATING FREEDOM FROM DISEASE AND EARLY DETECTION

10

RISK-BASED SAMPLING

The use of a *scenario tree* shall illustrate how risks of different population strata are captured in the analysis. Specificity is assumed 100% based on the argument that all positive samples are re-tested and, if still positive, the population is no longer considered free.

Let us consider Disease X for which freedom is defined as a 95% probability that the prevalence of infection is below 5% (design prevalence; P^*). Data from prevalence surveys showed that animals housed outdoor had a five times higher risk of being infected (HR group) than animals housed indoor (LR group) ($RR = 5.0$). The diagnostic test has a sensitivity (Se) of 95%. **Figure 25** depicts the structure of the underlying scenario tree, which includes a risk category, an infection and a detection node. This scenario tree also indicates which parameters are required at each node to calculate the overall branch probabilities. The input parameters and results are presented in **Table 13**.

At the risk category node, two probabilities are required:

1. The relative risk for that branch (RR), which is the ratio of the incidence or prevalence of infection in one group compared to another, and
2. The proportion of the population in that branch (PrP).

PrP and RR are combined into an adjusted risk (AR) based on Equation 1 and Equation 2 so that the average probability of infection for the entire population equals the design prevalence:

(continued on Page 100)

$$AR_{LR} = \frac{1}{(RR_{HR} \times PrP_{HR}) + PrP_{LR}}$$

Equation 1

$$AR_{HR} = AR_{LR} \times RR_{HR}$$

Equation 2

At the infection node, the *effective probability of infection (EPI)* of the D+ branches is calculated by multiplying AR by P* and that of the D- branches as 1-EPI_{D+} of the equivalent sub-branch. The EPI represents an adjusted probability of a unit within the respective branch being infected.

At the detection node, the probability of a positive test outcome is the probability of the terminal node and thus the branch probability (P(T+)). Since 100% specificity is assumed, P(T+ | D-) = 0 and P(T- | D-) = 1. For D+, the branch probabilities are calculated by multiplying the proportion of the surveillance component in that branch (PrSSC) with all the probabilities along the respective branch, i.e.:

T+: PrSSC x AR x P* x Se

T-: PrSSC x AR x P* x (1-Se),

whereby AR x P* = EPI.

The *component unit sensitivity (CSeU)* represents the probability that a single unit would return a positive outcome and is calculated as the sum of all T+ branches. For the current example the CSeU is 0.101 + 0.003 = 0.104 or 10.4%. The CSeU of risk-based sampling can then be compared to the CSeU of representative sampling, which is calculated as P* x Se = 0.05 x 0.95 = 0.0475, i.e. a probability of 4.75%. *The sensitivity ratio can be used to quantify the benefit of applying a risk-based over a representative strategy.* It is calculated as the ratio of the sensitivities between these two strategies, i.e. in case of the current example 0.104/0.0475=2.19. Meaning that the risk-based strategy is more than 2 times more sensitive than the representative sampling.

Best Practice Example 10. Risk-based sampling

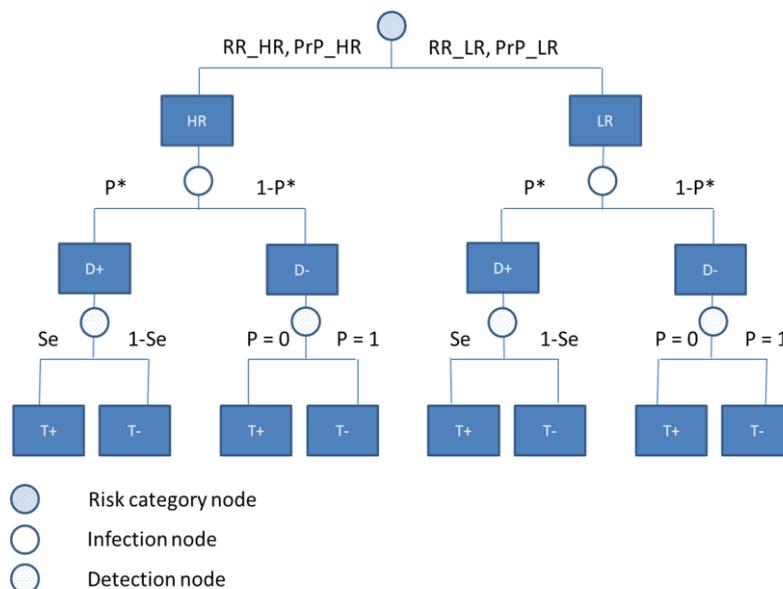


Figure 25. Scenario tree describing a surveillance component for disease X, which incorporates one risk factor (HR: high risk; LR: low risk), one infection node, and one detection node. The probabilities along each branch are calculated using the following parameters: Risk category node: risk ratio (RR) and proportion of units in each risk group (PrP); infection node; design prevalence (P*); detection node; test sensitivity (Se)

Table 13. Values used to calculate the probabilities for each branch

| TREE STRUCTURE | | | | INPUT PARAMETERS | | | | CALCULATED PARAMETERS | | | |
|----------------|--------------------|----------------|----------------|------------------|-----|-------|-----|-----------------------|------|-----|--------------|
| Branch no. | Risk category node | Infection node | Detection node | RR | PrP | PrSSC | P* | AR | EPI | SE | P(T+) |
| 1 | High risk | D+ | T+ | 4 | 0,2 | 0,05 | 0,9 | 2,50 | 0,13 | 0,9 | 0,101 |
| 2 | | | T- | 4 | 0,2 | 0,05 | 0,9 | 2,50 | 0,13 | 0,1 | 0,011 |
| 3 | | D- | T+ | 4 | 0,2 | 0,95 | 0,9 | 2,50 | 0,88 | 0 | 0,000 |
| 4 | | | T- | 4 | 0,2 | 0,95 | 0,9 | 2,50 | 0,88 | 1 | 0,788 |
| 5 | Low risk | D+ | T+ | 1 | 0,8 | 0,05 | 0,1 | 0,63 | 0,03 | 0,9 | 0,003 |
| 6 | | | T- | 1 | 0,8 | 0,05 | 0,1 | 0,63 | 0,03 | 0,1 | 0,000 |
| 7 | | D- | T+ | 1 | 0,8 | 0,95 | 0,1 | 0,63 | 0,97 | 0 | 0,000 |
| 8 | | | T- | 1 | 0,8 | 0,95 | 0,1 | 0,63 | 0,97 | 1 | 0,097 |

11

Let's consider a surveillance system that aims to provide at least 95% confidence of detecting disease X if it was present at a prevalence exceeding 0.02%. The surveillance system includes *three components* (C1, C2 and C3). Sensitivities of these individual components were estimated as 0.64 (CSe1), 0.86 (CSe2) and 0.73 (CSe3). The *overall sensitivity* of the surveillance system is calculated as

$$S_{Se} = 1 - ((1 - CSe1) \times (1 - CSe2) \times (1 - CSe3)) = 1 - 0.36 \times 0.14 \times 0.27 = 1 - 0.0136 = 0.986$$

Since this surveillance system *sensitivity exceeds 95%*, it is concluded that *the criteria to demonstrate disease freedom have been fulfilled*.

Best Practice Example 11. Combination of evidence from multiple components

12

Let us assume that surveillance of a population produced sufficient evidence at time t1 to conclude that the population is free from disease at *the target confidence level of 99%* (**Figure 26**). Subsequently, *the confidence level drops with each time step* (e.g. each month) until the next survey (e.g. at t₃) is carried out. However, instead of calculating the sample size to achieve the full target confidence level of 99%, the loss of the value of information is estimated for the time from the previous to the current survey to *estimate the remaining confidence level*. This remaining confidence level is the prior probability of freedom, which is used as input parameter to calculate posterior probability of freedom for the next survey. Hence, *sample size* is calculated to only achieve the difference between the remaining level of confidence and the targeted overall confidence level (x in Figure 26).

Best Practice Example 12. Risk-based requirement to calculate sample size

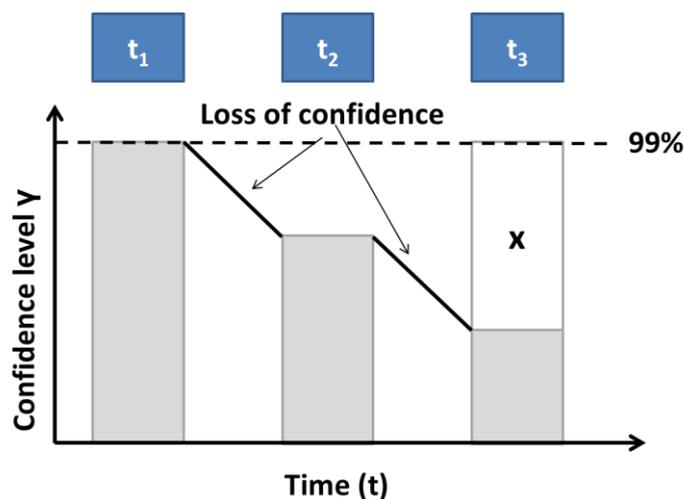


Figure 26. The methodology applying the concept of 'risk-based requirement' assumes that the probability of freedom (ProbFree) achieved at a given point in time (t_1) decreases over time until another survey is carried out (t_3) (adapted from Hadron, 2002). The survey at time t_3 only needs to reach that much confidence (x) to reach the desired overall confidence level of 99%

13

A country aims to use historical data to demonstrate freedom from *Trichinella* at a design prevalence of 0.0001% and a confidence of 95% (EC Regulation 216/2014; Article 3, number 3b). Continuous sampling of the pig population was first established in 1940 and the last case has been detected in 1970. The size of the slaughter pig population was kept constant at one million pigs per year to remove the influence of sample size on posterior probability of freedom. Please refer to **Table 14** for formulas, input parameters and references used.

With the assumption of perfect specificity, parameters are calculated as follows:

- *Posterior probability of freedom* (PostPFree): PostPFree at the end of each time period (TP) is obtained given prior probability of infection (PriorPInf) of the previous year and the component sensitivity of the previous year (CSe) (Martin et al. 2007b)
- *Component sensitivity* (CSe): CSe is calculated based on the expected number of infected animals under the design prevalence and the test sensitivity
- *Prior probability of infection* (PriorPInf): PriorPInf at t_1 is unknown and an uninformed prior of 50% is used as an estimate. At subsequent years, PriorPInf is derived from the posterior estimate at the end of $t-1$ by adding the probability of introduction of infection during the most recent time period (PIntro) and adjusting for the fact that it might have been present but undetected at the end of the previous TP.
- *Probability of introduction* (PIntro): Given that *Trichinella* has not been found since 1970, the probability of introduction can be estimated as one divided by the waiting time since the last outbreak (1970–2015) corresponding to $1/45 = 2.2\%$.

Results are shown in Figure 27. Despite the small slaughter pig population of one million pigs, a confidence level of 95% would have been achieved after 9 years of surveillance (PostPFree = 95.49%).

Best Practice Example 13. Risk-based requirement to calculate probability of freedom

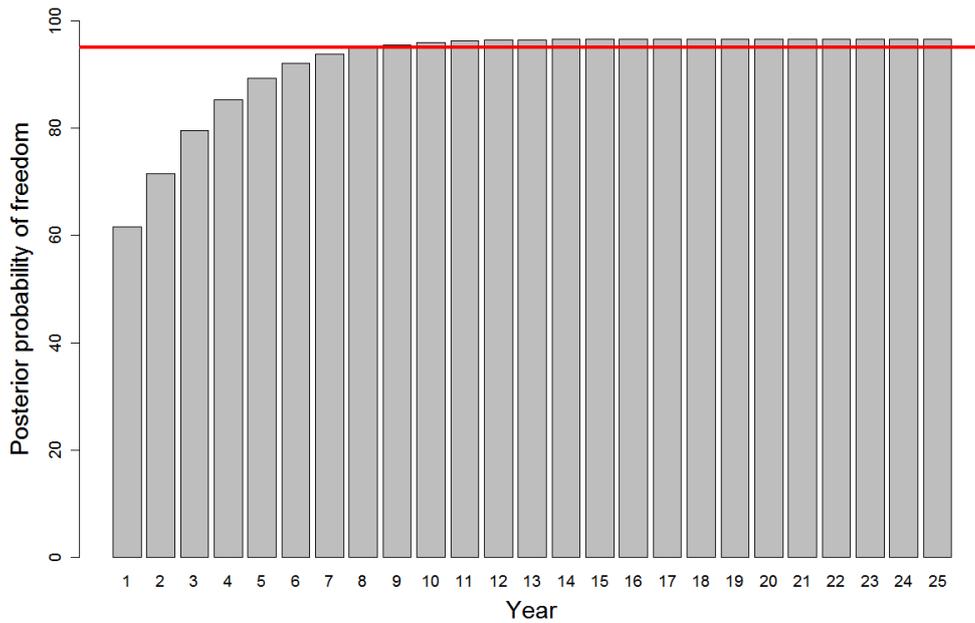


Figure 27. Posterior probability of freedom achieved over the course of 25 years

Table 14. Input parameters, formulas and sources used for Example 4 illustrating the application of riskbased requirements to demonstrate freedom from disease.

| ABBREVIATION | CALCULATION | VALUE | SOURCE |
|----------------------------------|---|-----------|---|
| P* | One infected pig per one million pigs tested | 0.0001% | EU Regulation |
| CL | | 95% | EU Regulation |
| N | One million pigs (constant) | 1,000,000 | [Fictive population with constant size] |
| Time since last detection | 1970-2015 | 45 years | |
| Test sensitivity | | 40% | Forbes et al. (1999) |
| D | $P^* \times N$ | 1 | |
| PIntro | One case divided by waiting time since the last outbreak (1970–2015) = 1/45 | 2.2% | Alban et al. (2008) |
| CSe | $1 - (1 - Se)^D$ | | Alban et al. (2008) |
| PostPInf(t) | Year1: PIntro Year2ff: $1 - \text{PostPFree}(t)$ | | Martin et al. (2007a) |
| PriorPInf(t) | Year 1: 50% Year 2ff: $\text{PostPInf}(t-1) + \text{PIntro}(t) - \text{PostPInf}(t-1) \times \text{PIntro}(t)$ | | Martin et al. (2007a) |
| PostPFree(t) | $\frac{1 - \text{PriorPInf}(t)}{1 - \text{PriorPInf}(t) \times \text{CSe}(t)}$ | | Martin et al. (2007a) |

ANNEX B – ECONOMIC EVALUATION

ADDITIONAL EXPLANATION FOR FIGURES 20 AND 21 (SECTION 8.1.1)

Please see [Figures 20 and 21](#) in [Section 8.1.1](#).

Once least-cost combinations are plotted in relation to levels of loss avoidance (A1 to An), an expansion path can be identified, i.e. a line through all the tangent points on loss avoidance curves with the corresponding budget lines for surveillance and intervention. The *economic optimum* or in other words the *maximum net benefit for society* can be found where the marginal loss avoidance (i.e. marginal benefit) equals the marginal costs on the expansion path.

To identify this economic optimum for disease mitigation, it is necessary to understand the technical relationships between loss avoidance, and the use of surveillance and intervention resources and the valuation (pricing) of the resources. The *valuation* is used to translate loss avoidance and resource use into monetary values such as benefits and costs. Then, least-cost combinations for surveillance and intervention can be determined and the *least-cost combination(s) identified* that are consistent with the avoidance loss that maximises economic welfare.

DETAILED EXPLANATION OF ECONOMIC EVALUATION TECHNIQUES (SECTION 8.2)

The economic evaluation techniques discussed in Section 8.2 are discussed here in more detail. For the convenience of reading the parts under 8.2 are repeated here and expanded. Table 12 provides an overview.

Table 12. Comparison of full and partial economic valuation techniques. Modified based on Drummond, 1997

| Is there a comparison of two or more alternatives? | Are both costs and consequences of the alternatives determined? | | |
|--|---|----------------------------|--|
| | NO | NO | YES |
| | | EXAMINES ONLY CONSEQUENCES | EXAMINES ONLY COSTS |
| | | Outcome description | Cost description |
| | | Effectiveness assessment | Cost assessment |
| | YES | | Cost-outcome description Cost-effectiveness analysis Cost-benefit analysis Least-cost analysis ¹ (Cost-utility analysis) (Optimisation analysis) |

¹ Listed in this cell, because in most surveillance systems the outcome needs to be measured as well.

Cost Benefit Analysis (CBA)

In a CBA, it is important to quantify both the costs and benefits (avoided losses) of a mitigation programme *in monetary terms*. Social CBA refers to the impact assessment of a programme on societal level, these impacts may be economic, environmental, biological and medical (Rushton et al., 1999) and include externalities (e.g. shadow prices). In *animal health*, social CBA is rarely used, the more popular method is *financial CBA* where all costs and benefits are valued based on market price and subsidies are seen as an income stream. These CBA often relate to infectious disease (epidemic and endemic) and its control (i.e. avoidance of disease losses); only few publications are available that explicitly assess the value of surveillance. Losses that are caused by disease and can be avoided with surveillance and intervention are for example mortality, abortions, reduced milk yield or reduced egg production. Moreover, expenditures for interventions are extra resources used as a consequence of the disease (e.g. vaccines, veterinary services, drugs) that can be avoided and are therefore part of the benefit.

KEY STEPS IN A CBA are to:

1. Identify surveillance options to be compared (note that an option can be the “no surveillance” scenario = the baseline)
2. For each programme, identify the steps requiring financial inputs (costs of surveillance and of intervention)
3. Identify all the potential losses incurred by the disease for all options
4. Measure and value the costs and the benefits (losses avoided) in the same monetary unit
5. Compare the costs and benefits between the different programme options

THREE ACCEPTABILITY CRITERIA are commonly used in CBA to determine whether the benefits stemming from a mitigation policy at least cover its costs, thus making a strategy justifiable. Those are: *net present value* (NPV), *benefit-cost ratio* (BCR) and *internal rate of return* (IRR); relevant equations can be found for example in (Thrusfield, 2005).

EQUATIONS FOR THE THREE ACCEPTABILITY CRITERIA:

Net present value: The NPV is the difference between the sum of the present value of the benefits (B) and the sum of the present value of the costs (C) and should be positive for an investment to be worthwhile (t=time in years; r=discount rate):

$$NPV = \sum \frac{B_t}{(1+r)^t} - \sum \frac{C_t}{(1+r)^t}$$

Benefit-cost ratio: The BCR is the ratio between the sum of the present value of benefits and the sum of the present value of costs and should be ≥ 1 for an investment to be worthwhile:

$$BCR = \frac{\sum \frac{B_t}{(1+r)^t}}{\sum \frac{C_t}{(1+r)^t}}$$

Internal rate of return: The IRR is the discount rate that will make that net present value zero. If the IRR is bigger than the minimal acceptable discount rate, the investment is considered worthwhile. It is calculated by solving for r such that:

$$NPV = \sum \frac{B_t}{(1+r)^t} - \sum \frac{C_t}{(1+r)^t} = 0$$

When *conducting a cost-benefit analysis of surveillance*, the following should be taken into account:

- Disease reduction (=loss avoidance) can only be achieved *if surveillance and intervention are considered together*, as surveillance on its own does not reduce disease. Surveillance is inextricably linked to intervention and so the assessment of loss avoidance stemming from disease management should be placed in the context of the overall disease mitigation process, as seen for example in (Häsler et al., 2012b; Kompas et al., 2006; Moran and Fofana, 2007; Roman Carrasco et al., 2010).
- To be able to estimate the avoided losses, it is necessary to *know what the disease progression looks like under different mitigation options*. Both the strategy under evaluation (e.g. the implemented one) as well as the counterfactual (or baseline, i.e. the situation that would occur without the implemented strategy) can be highly dynamic depending on the disease and context. Therefore, the *use of epidemiological simulation models* is recommended to simulate disease dynamics under different surveillance scenarios and produce proxy measures of loss avoidance over time (e.g. number of animals infected, prevalence, etcetera.) that can then be translated into values.
- The *timeline of the surveillance system to be evaluated* needs to be chosen carefully taking into account the planning, implementation and evaluation horizon. For example, if the endpoint of the programme is the elimination of disease from a population, the analysis will not have to take into account post-elimination surveillance costs to monitor freedom from disease. However, if the time span of the investment to be assessed includes the post-elimination period, the costs of long-term surveillance to sustain the free status and the costs of potential re-incursions of disease will also have to be considered (Häsler et al., 2011).

WEAKNESSES OF CBA:

- a) Large projects (e.g. survey of the whole national population) give high net present values (NPVs) and need large investments; there may be several other smaller projects that yield higher benefit-cost ratios (BCRs) and internal rates of returns (IRRs). Much depends on whether the one large project replaces a smaller higher yielding project or whether the smaller project can be applied several times or alongside other smaller and higher yielding projects.
- b) BCRs change if some costs are subtracted from benefits before overall benefits and costs are added up and the BCR calculated. This usually increases the value of the BCR. It happens often in the veterinary field, because there is a tendency to look at the costs of the government veterinary services or of a project as against the increase in income to farmers/livestock producers. But livestock producers have their own costs (time, extra costs of keeping livestock, cost of applying new disease control measures) and these should, strictly speaking, be added to government/project costs. However, they are often subtracted from the extra livestock output to give net benefits or income to producers and these are treated as 'the benefits'.
- c) IRRs can be artificially high - over 100% - for projects where there is very little 'up-front' expenditure. This happens often in the animal health field where a regular intervention yields a regular benefit without a lot of investment at the start – e.g. a vaccination programme. (This is the opposite of the disease eradication scenario, where a lot of expenditure up front yields benefits in perpetuity, but a relatively low IRR). Of course IRRs cannot be calculated at all if the benefits are larger than the costs every year of the project.

STRENGTHS OF CBA:

- a) NPV provides information on how much money is gained, over and above the minimum cut off (the discount rate).
- b) BCR is unaffected by project size
- c) IRR gives an average annual percentage return over the life of the project and helps to identify a cut-off or minimum acceptable percentage return (the discount rate). Both NPV and BCR depend on the discount rate.

IN SUMMARY

CBA compares the total discounted benefits of a project in monetary units with its total discounted costs in monetary units and recommends the implementation of the project if the benefits exceed the costs. It includes the definition of the useful life of the project or programme, estimating physical units of benefits (e.g. losses avoided) and costs (e.g. mitigation resources used), translation of the physical units into economic values, the conversion of future values into present values by discounting, and finally the calculation of the choice criteria described. All three choice criteria provide different information and it is therefore recommended to look at the three of them in conjunction.

Cost Effectiveness Analysis (CEA)

Cost-effectiveness analysis aims to assess the outcome of a programme *in non-monetary units* in relation to its cost. Contrary to CBA where the benefit is expressed in monetary terms, in CEA *the outcome is expressed in non-monetary terms*. In human health economics the outcome often refers to the avoidance of illness or death, while in animal health other technical measures such as the detection probability of cases of disease or number of abortions avoided.

Unlike in health economics, where attempts have been made to harmonise CEA methodologies and encourage comparability of studies (Murray, Evans, Acharya, & Baltussen, 2000), *there are no specific guidelines available yet for its application in animal health*. Whenever possible, the measure of effectiveness *should reflect a final outcome* and not an intermediate outcome, even though the use of an intermediate measure is valid if it has a value on its own (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005). If a final outcome is considered such as the number of livestock dying or a change in milk yield, the value is already monetized, as animals have a price as do their products and a the result of a CEA is directly interpretable (e.g. cost per cow death avoided).

However, given resource and technical constraints, there is a demand in the surveillance community to *include intermediate outcomes* instead of final outcomes in CEA. For instance, an effectiveness measure such as timeliness may be considered *to be a proxy for the final outcome or benefit*, such as loss avoidance and reduced intervention expenditures due to earlier outbreak detection (which would be measured explicitly in a CBA). *However, CEA of surveillance can inform resource allocation meaningfully only if the effectiveness measure has an interpretable value*. For example, the value of timeliness may have been established in studies of past outbreaks to know that each day of earlier detection of a highly pathogenic avian influenza (HPAI) outbreak resulted in the avoidance of losses worth £100,000. In such a case, a cost-effectiveness ratio of a surveillance system to early detect HPAI expressed as costs/days of earlier detection can be easily interpreted. However, without this information, effectiveness measures like 'time of introduction of disease until detection' or the 'probability of detecting an outbreak' are not informative in a CEA.

Therefore, before conducting a CEA, it is necessary to think carefully about how the findings can be interpreted and whether the value of an effectiveness measure can be compared to the additional costs.

THREE TYPES OF COST-EFFECTIVENESS RATIOS are corresponding to different uses:

Average cost-effectiveness ratio (ACER)

If we are looking at surveillance options that are *non-competing* (i.e. they can be implemented in parallel) or we are only looking at one single surveillance option, the following approach applies: Calculation of the *average cost-effectiveness ratio* (=divide the net cost of surveillance by the effectiveness) of each option and then gradual implementation of options starting from the one with the lowest cost per unit outcome until the budget is used.

$$ACER = \frac{Total\ costs_{Surveillance\ A}}{Total\ outcomes_{Surveillance\ A}}$$

NOTE: Need to use the same effectiveness metric for the outcomes for all options.

Incremental cost-effectiveness ratio (ICER)

More often we are faced with a situation where we have several surveillance options that are competing for the same resources and we can choose only one - in other words they are *mutually exclusive* (e.g. use risk-based surveillance or conventional surveillance). This could be of interest when looking at replacing the present surveillance system with a new system or when assessing a set of options when planning a new surveillance system.

$$ICER = \frac{Total\ costs_{Surveillance\ A} - Total\ costs_{Surveillance\ B}}{Total\ outcomes_{Surveillance\ A} - Total\ outcomes_{Surveillance\ B}}$$

For this, the incremental cost-effectiveness-ratio (ICER) should be used, which allows determining the marginal or incremental cost for an additional unit of outcome measure when choosing between different surveillance options. It measures the *additional* cost per *additional* outcome. NOTE: Need to use the SAME effectiveness metric for all options.

Marginal cost-effectiveness ratio (MCER)

The marginal cost-effectiveness ratio assesses the specific changes in cost and effect when a programme is *expanded or contracted* (e.g. the additional costs of surveying 10 more farms without changing the surveillance design). This helps to identify the point of optimal level of a surveillance system where the largest overall benefit is produced – it therefore follows the same basic concept as optimisation. It defines the level where most health effects are reached at lowest costs according to the following equation:

$$MCER = \frac{Total\ costs_{Surveillance\ A+1\ unit} - Total\ costs_{Surveillance\ A}}{Total\ outcomes_{Surveillance\ A+1\ unit} - Total\ outcomes_{Surveillance\ A}}$$

Least-cost analysis (LCA)

In this type of analysis, *the cost is the dominant determining factor* in a choice between different options, because the outcome or the value of the outcome is the same for each option. The valid application of the method depends on establishing that the cost is indeed the determining factor and that the effectiveness is the same for the surveillance options to be compared.

TWO GROUPS - Least-cost analysis in surveillance can be categorised broadly into two groups:

1) *Comparison of different surveillance options that achieve a defined target in terms of effectiveness*

E.g. demonstrate with a confidence of 95% that a country is free from a disease or achieve a sensitivity of detection of 80%. For this economic evaluation, it is necessary to first establish the equal effectiveness using relevant methods. Next, the costs of all equal options can be calculated and the options be ranked according to costs. By adopting the least-cost of equal surveillance options, the highest net benefit can be achieved.

An example where this approach can be of interest is where outcome-based standards require a minimum effectiveness and several surveillance designs may be possible. In such a case, it is necessary to assess whether the different designs achieve the required outcome and to calculate the surveillance costs for all those that do achieve the target. The surveillance option with the least cost is the one that achieves the highest economic efficiency and is the one that should be chosen if only economic considerations apply.

2) *Where the surveillance protocol is given by for example legislation*

E.g. definition of the types and number of farms and samples, laboratory testing and analysis procedures are described), it can be expected that the surveillance component achieves the desired effectiveness. Different surveillance options to be compared then can only look at changes in the implementation of the surveillance (e.g. use cheaper test tubes from a different manufacturer, use synergies between programmes) and select the option that complies with the given requirements at minimum cost.