Project no. 310806

Providing a new generation of methodologies and tools for cost-effective risk-based animal health surveillance systems for the benefit of livestock producers, decision makers and consumers

KBBE
Collaborative Project
FP7-KBBE-2012-6

http://www.fp7-risksur.eu

Deliverable No. 1.5

Data collection protocols and guidelines

WP 1 – Development of a conceptual evaluation framework

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Submission Date: December 2013
Type: Deliverable

Table of Contents

Table of Tables

Table of Figures

Abbreviations

AD	Aujeszky disease
AHS	African horse sickness
AHVLA	Animal health and veterinary laboratories agency
AI	Avian influenza
AMR	Antimicrobial resistance
ASF	African swine fever
BE	Belgium
BG	Bulgaria
BHV-1	Bovine herpesvirus type 1
BRUC	Brucella
BSE	Bovine spongiform encephalopathy
BT	Bluetongue
BVDV	Bovine viral diarrhea
CBPP	Contagious bovine pleuropneumonia
CEM	Contagious equine metritis
CH	Switzerland
CIRAD	Agricultural Research for Development (French: Centre de coopération internationale en recherche agronomique pour le développement)
CSF	Classical swine fever
CZ	Czech Republic
D	Deliverable
DE	Germany
DK	Denmark
DOW	Description of work
EAV	Equine arteritis virus
e-C trade	Extra-community trade
EIA	Equine infectious anaemia
EBL	Enzootic bovine leukosis
ES	Spain
ESNIP	European Surveillance Network for Influenza in Pigs
FlaviV	Flavivirus
FLI	Friedrich-Loeffler-Institute, Germany
FMD	Foot and mouth disease
FR	France
GD	Animal health services Deventer (Dutch: Gezondheidsdient voor Dieren)
GR	Greece
HR	Croatia
IT	Italy
IBR	Infectious bovine rhinotracheitis
i-C trade	Intra-community trace
IE	Ireland
NO	Norway
ND	Newcastle disease
NL	Netherlands
ParaTB	Paratuberculosis
PL	Poland
PRRS	Porcine reproductive and respiratory syndrome virus
RB	Risk-based
RVC	Royal veterinary college
SAFOSO	Safe Food Solutions (Swiss consultancy and capacity-building company)
SE	Sweden
SVA	Swedish National Veterinary Institute (Swedish: Statens veterinärmedicinska anstalt)
SVD	Swine vesicular disease
TB	Tuberculosis
TSE	Transmissible spongiform encephalopathy
UCM	Complutense University of Madrid (Spanish: Universidad Complutense de Madrid)
UK	United Kingdom
WP	Work package

1 Abstract

The RISKSUR project aims to develop a conceptual generic framework for animal health surveillance system evaluation and provide decision making support for informing the design of risk-based surveillance. The application of consistent surveillance terminology is crucial to ensure robust data quality and facilitate comparability of surveillance systems. In recent years, efforts have been made to standardize terminology for animal health surveillance based on the outcome of a pre-ICAHS workshop in 2011 involving renowned surveillance experts. This terminology was applied in two tasks describing public and private surveillance systems, the mapping (Task 1.1) and the review (Tasks 2.1, 3.1 and 4.1). Data collection illustrated limitations of how surveillance is currently documented and highlighted inconsistencies in the interpretation of terminology and instructions. Subsequent consistency checks stimulated discussions to refine surveillance terminology, particularly related to surveillance component, means of data acquisition, risk-based sampling, surveillance purpose and multi-objective surveillance. Seven country representatives involved in data collection filled out a questionnaire estimating the input required collecting the data, the extent to which surveillance was documented and contacts collaborated, the clarity of instructions and the completeness of public and private surveillance data. This report describes the results of consistency checks, revised definitions/decision criteria and current limitations of information describing surveillance activities. It is recommended to further refine definitions and guidelines related to surveillance and in particular to risk-based surveillance as part of the RISKSUR project to promote the use of consistent terminology in the future. The mapping data collection and subsequent consistency checks were crucial elements of the early RISKSUR project as it highlighted limitations in the documentation of surveillance systems and surveillance terminology. It would be a useful outcome of the project to further refine surveillance terminology and document results in a manual illustrated with practical examples. Early input from external experts could be obtained by encouraging general feedback through a blog on the RISKSUR website and subsequently validating recommendations by means of a questionnaire targeting experts from various sectors.

Key words: Animal health, surveillance, terminology, definitions, risk-based, documentation.

2 Background

The RISKSUR project aims to develop a conceptual generic framework for animal health surveillance system evaluation and provide decision making support for informing the design of risk-based surveillance. It includes eight work packages (WPs), which are strongly interlinked (Figure 1). WP 1 focuses on the development of a conceptual generic evaluation and decision-making framework to inform the development of specific decision support frameworks and associated tools in WPs 2-4. WPs 2-4 deal with the surveillance objectives "Early detection", "Demonstration of freedom from disease" and "Prevalence estimation and case detection for endemic diseases", respectively. WP 5 develops frameworks and methods for the integrated epidemiological and economic evaluation of surveillance for those three objectives. Case studies are used to validate the frameworks and tools developed in the RISKSUR project in relation to their ability to

- Inform the surveillance and epidemiological design;
- Assess epidemiological performance; and
- Assess cost-effectiveness.

Applications assisting the implementation of the methods developed will be produced in WP 6. The dissemination of knowledge including training is done in WP 7. All these activities are managed and coordinated under WP 8.

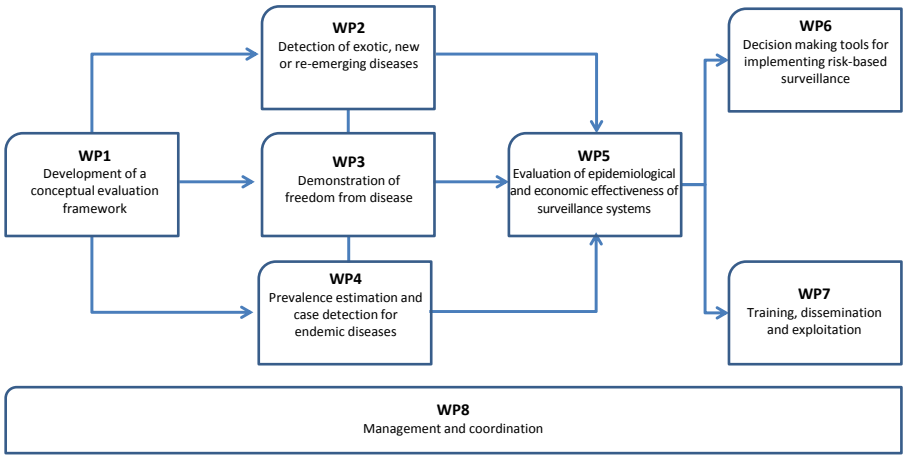

Figure 1. Illustration of the structure of RISKSUR, which includes eight work packages (WPs). Adapted from the RISKSUR project factsheet.

In **Year 1**, the main focus of the project was on tasks in WP 1 as well as descriptive tasks in WPs 2-4. These included:

1. Mapping of populations, trade flows, infrastructure, surveillance systems and decision making processes (Task 1.1);
2. A systematic review of methods and frameworks for economic evaluation (Task 1.2);
3. A survey to prioritize and weigh evaluation attributes and criteria (Tasks 1.3);
4. The development of an evaluation matrix (Task 1.4);
5. A systematic review (Tasks 2.1, 3.1 and 4.1) of
    a. Peer-reviewed literature; and
    b. Surveillance systems; and
6. The selection of case studies (Task 2.2.1).

Points 1 and 5b are subsequently referred to as descriptive tasks related to surveillance systems. The objective of **Task 1.5** and its related deliverable **D 1.5** was to define integrated data collection protocols and mechanisms to ensure robust data quality. The project plan further prescribes that data needs shall be established for epidemiological and economic criteria defined in the evaluation matrix developed under Task

1.4 (see p. 7 of the DOW). This shall help developing generic integrated data collection protocols and guidelines, thereby ensuring integration of economic and epidemiological analyses and promoting synergies between activities. The delivery month of the evaluation matrix (D 1.4) and its data collection protocols (D 1.5) were both set for Month 12 (see p. 23 of the DOW). However, the evaluation matrix was developed without circulating drafts in advance so that data needs for its epidemiological and economic criteria could not be established in time. In discussion with CIRAD, leader of D 1.4, it was agreed that Tasks 1.5 and 5.2 overlap as Task 5.2 (Months 6 – 24) also foresees the development of standardised protocols for the evaluation matrix. The difference is that Task 1.5 focused on epidemiological and economic criteria and Task 5.2 on data collection and analysis. It was agreed that the data collection protocols for the evaluation matrix would be developed in Task 5.2.

At the end of June, 423 surveillance components had been submitted for the mapping of surveillance systems in partner countries. A preliminary report on these mapping data submitted on 1 August (D 1.1) identified considerable inconsistencies between countries in how data about surveillance systems were collected. To rectify this and achieve consistency in the dataset, it was suggested to develop refined protocols under Task 1.5 for variables covered in the mapping (Task 1.1) and review of surveillance systems (Tasks 2.1, 3.1 and 4.1), the descriptive tasks listed above as points 1 and 5b. This suggestion was approved by the project team at the annual project meeting on 16 October 2013.

The revised objectives of Task 1.5 were to describe the final design adapted for the mapping and review, document the results of consistency checks as well as revised definitions and discuss the current limitations of information describing surveillance (Figure 2). Therefore, the output of Task 1.5 will also form a basis for the development of:

- A framework and associated tools to inform the design of surveillance systems (Tasks 2.2.2, 3.2.2, 4.2.2), and
- Data collection protocols for the evaluation matrix (Task 5.2).

This change in the objective of Task 1.5 does not affect the work that will be carried out in WPs 2-4 as they focus on the epidemiological rather than the economic evaluation. The aim to ensure integration of economic (WP 5) and epidemiological analyses (WPs 2-4 and WP 5) could now not be fulfilled in Task 1.5. Teleconferences or face-to-face meetings will be organized between members of WPs 2-5 from early 2014 onwards to ensure a stronger link between the surveillance evaluation framework (WP 5) and the surveillance design framework (WPs 2-4).

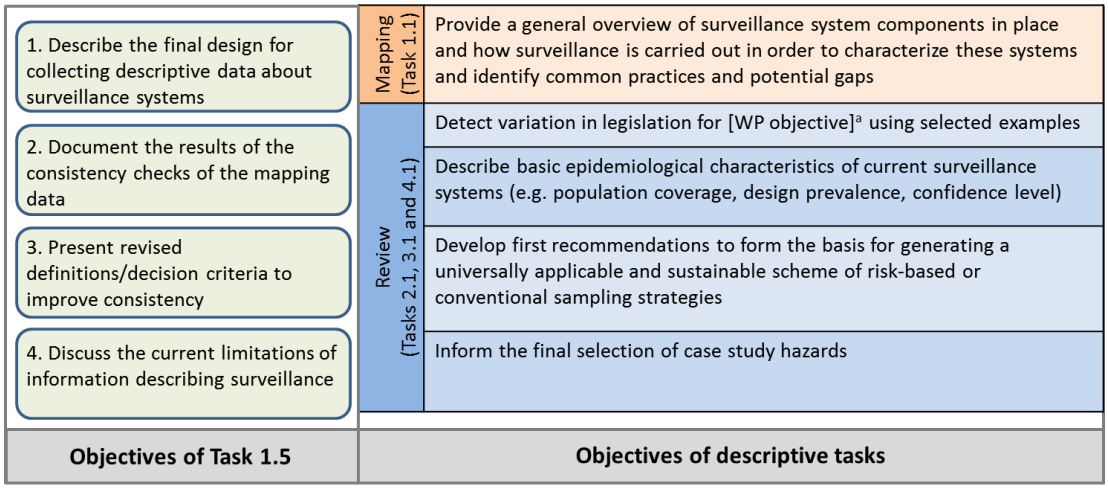

Figure 2. Objectives of Task 1.5 and descriptive tasks of surveillance systems (mapping and review). Descriptive tasks were carried out in representative EU member states. [a] [WP objective]: WP2: Early detection of exotic, new, or re-emerging disease; WP3: Demonstration of freedom from disease; WP4: Prevalence estimation and case detection for endemic disease.

3 Materials and Methods

The **objectives** of the descriptive tasks are shown in Figure 2.

Design of data collection protocols and guidelines: For the mapping, RVC, leader of Task 1.1, designed the data collection protocols and guidelines as well as the databases in collaboration with consortium members. For the review, FLI, leader of Task 1.5, coordinated email exchanges with main partners (AHVLA, RVC, SVA, UCM) and Skype discussion with all partners (also including CIRAD, GD and SAFOSO. Based on the partners' input, data collection protocols and guidelines were developed.

Data sets: The 26 and 23 variables included in the mapping and review, respectively, are described in Table 6 and Table 7. Surveillance systems were split into components. A component was defined as "a single surveillance activity used to investigate the occurrence of one or more hazards or health events in a specified population, which has a self-contained surveillance protocol that focuses on a particular data source." Components were recorded at the national (NUTS0) level, although regional and local programs could also be included. If programs differed between regions, a representative example was to be provided together with an indication of the extent of regional variation. The year 2011 was targeted as reports on surveillance results for the year 2012 were not expected to be available when data collection started in April 2013.

Inclusion criteria: It was encouraged to include public and private surveillance components. The mapping covered all hazards (e.g. pathogens, antimicrobial resistance, animal welfare) and species (e.g. bees, livestock, pets, wildlife, zoo animals, vectors), whilst the review focused on those hazards (and affected species) considered for case study selection as of July 2013 (Table 5). This reduced list of case study hazards has been compiled following the collection of data from partner countries on data availability and expertise under the case study selection tasks (task 2.2.1).

Geographical coverage: Seven partner countries (CH, DE, ES, FR, NL, SE, UK) and eight non-partner countries (BE, BG, CZ, DK, GR, HR, IT, IE) were included. The non-partner countries were selected by a combined assessment of the following factors:

- Economic and political importance;
- Availability of official contact person and their responsiveness;
- Similarity of animal populations, production systems, and hazards present/absent with already covered countries (Ripperger, 2013b).

Due to the effort required in describing surveillance systems and the different level of cooperation, the work was divided to cover partner countries in Stage 1 and non-partner countries in Stage 2 of data collection.

Time of data collection: For mapping, data collection started in February 2013 and was supposed to finish in March 2013. However, the workload involved in collecting the Mapping data exceeded by far the expectations so that the deadline for data collection was set for the end of May and October 2013 for partner and non-partner countries, respectively (Ripperger, 2013a). After submission of the initial data set at the end of June 2013, a draft report for the mapping (D 1.1) was submitted on 1 August (Ripperger, 2013a).

Consistency checks: Between 18 October and 22 November 2013, the data used for the draft mapping report (termed "initial data set") was checked for consistency to identify inconsistencies in interpretation of guidelines and data recording. Components relating to salmonella (FLI), bovine TB (UCM), brucellosis (UCM), avian influenza (SVA), passive surveillance (SVA) and multi-objective surveillance (SVA) were compared based on the definitions of the data collection protocol and specifications of EU regulations. Summary documents were sent to partners involved in data collection for comments (AHVLA, CIRAD, FLI, GD, RVC, SAFOSO, SVA and UCM). Key issues were subsequently discussed by email and Skype in small group discussions first (AHVLA, FLI, RVC, SVA and UCM) and with all partners via Skype thereafter to agree on more specific definitions and decision criteria for surveillance components and variables. Following

agreement, written guidance was prepared and circulated among contributing consortium members. Sixty-four EU-regulated components were listed for the hazards AI, AMR, Brucella, BSE, BT, bTB, EBL, Salmonella, Scrapie, Trichinella, hazards covered in AI centres, hazards relevant to aquaculture and zoonotic pathogens as illustrations of how to implement these recommendations based on mandatory components. However, these EU-regulated components were only examples as national legislations may deviate from the proposed procedures depending on the hazard situation or due to other reasons (e.g. stricter national regulations). All partners then adjusted their (country-specific) part of the data set accordingly (termed "revised data set").

Questionnaire: A questionnaire was developed with the aim to summarize general problems encountered when documenting surveillance systems for partner and non-partner countries. The questionnaire included five questions (see Section 7.2.3) estimating the input required collecting the data, the extent to which surveillance was documented and contacts collaborated, the clarity of instructions and the completeness of public and private surveillance data.

Data management and analysis: Data for the mapping were initially entered into a Web database to ensure data confidentiality. After all data of the original data set had been entered, data were recoded, validated and managed in Microsoft Access. Graphs were prepared in Excel for the mapping and in R version 3.0.1 (R Development Core Team: www.r-project.org) for this deliverable report.

4 Results

4.1 Mapping

The following topics were interpreted differently in the initial dataset and highlighted for discussion during consistency checks:

- Component splitting;
- Means of data acquisition (active, passive or enhanced passive);
- Surveillance purpose;
- Risk-based sampling; and
- Multi-objective surveillance.

Interpretation of the term surveillance component:

Salmonella was chosen as example hazard to evaluate how surveillance systems were split into surveillance components as this hazard is strictly EU regulated for chickens and turkeys and had the largest recorded number of components. Figure 3 illustrates the variability between countries in how components were recorded. Countries 1 and 3 had entered many components (both: n = 22), but only for chickens and turkeys (Country 1) as well as pigs (Country 3). In contrast, Countries 5 (n = 17) and 6 (n = 7) entered components also for other species including cattle, poultry in general, feed, wildlife and multiple species.

The original data collection protocol defined a component according to four criteria based on Hoinville (2013):

1. A single activity;
2. Using a particular data source;
3. Focused on a specified population;
4. Targeting one or more hazards.

The documentation of the RISKSUR design framework (see Section 7.3.1) elaborates further on the proposed link to the epidemiological design and data generation process.

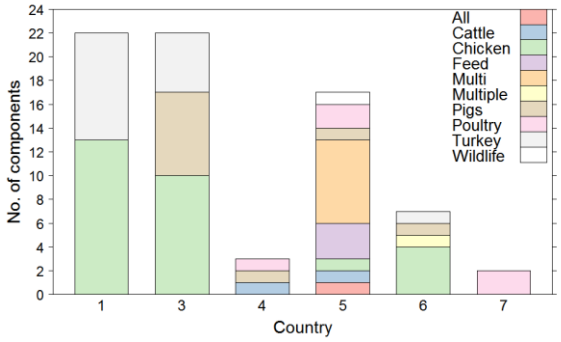

Figure 3. Number of components recorded for Salmonella by species and country (*n* = 71).

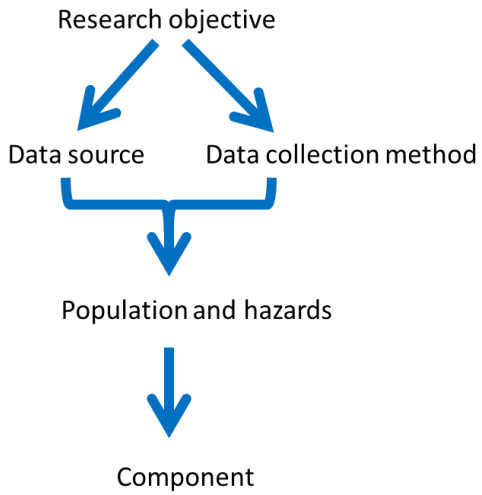

Figure 4. Determinants for the splitting of a component.

Partners had different views on how the terms “single (surveillance) activity” and ”specified population” should be interpreted. Following discussions, it was agreed that the data source and data collection method (rather than the term “single activity”) should determine what is defined as a component, which in turn will depend on the research objective. Differentiating variables of the data source and data collection method would then define how the population covered and the hazards included should be specified (Figure 4).

The component definition for the mapping was subsequently revised, specifying distinguishing variables for data source and data collection method taking into account the mapping objective (criteria 3 and 4).

1. Hazard(s): Threat, disease focus or health event
2. Specified population: Species and target sector
3. Data source: Sampling point, case definition
4. Data collection method: Means of data acquisition, study design, risk-based sampling

Apart from differences in hazard and population, each component should differ in at least one of these five distinguishing variables (green font colour).

Subsequently, it was acknowledged that the stratifying variables used in the analysis carried out for the mapping report needed to be considered as further differentiating criteria. Hence, instructions were given to separate hazards and species in principle, apart from cases where the surveillance protocol does not justify a separation.

Table 1. Agreements on inclusion or exclusion of specific aspects for the mapping.

Aspect	Decision
Testing of animal feed	Include
Antimicrobial resistance	Include
Testing of meat and meat products	Exclude if testing is done for food safety rather than to assess animal health
Testing in artificial insemination stations	Include
Movement testing	Include
Environmental testing	Include
Export examinations	Exclude; will be covered in the text part of the mapping

Numerical variables (i.e. expenditure) are not always reported at the same level of detail as the components are split. In that case, instructions were given to enter the information to that component with the highest contribution and add a comment what other components are covered by this information.

In this context, the in-/exclusion of general aspects that were handled differently between countries was also agreed on (Table 1).

Means of data acquisition: Passive, enhanced passive and active surveillance

The number of passive and enhanced passive surveillance components differed between countries (Table 2). The entered hazards indicated reasons for those differences. Components were sometimes listed

- Separately for individual livestock species (Countries 2, 6, 7) or wildlife (Countries 2, 4, 5, 7),
- For notifiable (Countries 2, 4, 6), emerging (Countries 4, 5, 6) or several diseases (Country 6), in general, and
- Specifically for individual hazards. No pattern could be detected as to why some hazards were listed individually and others not.

Table 2. Number of passive (1st number in brackets) and enhanced passive components (2nd number) entered in the initial database by country. If no numbers are displayed, only one passive component had been entered.

Country	N components		Hazard (group) or species (group)
	Passive	Enhanced	
1	14	-	AI (2/0), ASF, BSE, CBPP, CSF, EBL (2/0), FlaviV (2/0), Scrapie, SVD, TB
2	22	-	AI (2/0), ASF, BRUC, BSE, BT (2/0), CSF (2/0), EAV, Fish (2/0), FlaviV, FMD, Notifiable, ParaTB, Rabies (3/0), Scrapie, Tularemia, Wildlife
3	0	-	
4	14	-	BRUC, CSF, EBL, Emerging (2/0), IBR, Many (3/0), Notifiable, Scrapie, TB, Toxins, Wildlife
5	26	**3**	AD, ASF, Atrophic rhinitis, BRUC, BSE, BT, Clinical, CSF, Emerging (2/0), FlaviV (0/**1**), Fish (2/0), IBR, ParaTB (1/**1**), PRRS, Q Fever, Rabies, Salmonella (2/0), Scrapie, Shellfish (3/0), Swine influenza (0/**1**), SVD, TB, Wildlife
6	12	**14**	AMR, BRUC (2/**1**), Cattle (2/**1**), Contag. agalactia (0/**1**), Emerging (0/**1**), Genetic (0/**1**), Influenza, Notifiable (0/**1**), Pigs (2/**1**), Salmonella (1/**1**), Scrapie (0/**1**), Several diseases, Sheep, TB (0/**1**), Welfare
7	71	-	AD, AHS, AI, AMR, Anaplasmosis, Anthrax, ASF, Bees (3/0), Botulism, BRUC (5/0), BSE, BT, CBPP (2/0), CEM, Chlamydia, Crustaceans, CSF, Dourine, EBL, Equines, EIA, Equine Encephalitis, ESNIP, EVA, Fish, FlaviV, FMD, Glanders, Haemorrhagic septicaemia, Heartwater, Hypodermosis, Japanese encephalitis, Lumpy skin, Lympangitis, Molluscs diseases, Mycoplasma, Nairobi sheep disease, ND, ParaTB, Peste des petits ruminants, Pox (2/0), Primates, Pullorum disease, Q fever, rabies, (2/0), Rift Valley, Rinderpest, Salmonella, Schmallenberg, stranding, Surra, SVD, TB (3/0), Teschen, Theileria, Trypanosoma, TSE, Tularemia, Vesicular stomatitis, Wildlife

First, it was proposed to list a general passive component for each species (cattle, sheep, goats, pigs, poultry, fish, equidae, wildlife, wild birds, horses, companion animals) or species group and only list enhanced passive components by hazard. However, this would have meant that all countries would enter the same passive surveillance components. Therefore, it was decided to only cover enhanced passive components and provide a descriptive summary of the passive surveillance (i.e. for notifiable diseases) for the countries covered.

Discussions were held about how to apply the definition for enhanced passive surveillance by Hoinville, et al. (2013). The following set of criteria was agreed on, either of which would justify a component to be termed as “Enhanced passive” for the purpose of the mapping:

1. Generally applicable to any form of surveillance that makes further use of passively collected data, such as scanning surveillance and syndromic surveillance
2. Passive surveillance with any form of specific enhancement (awareness, education, encouragement to report) such as
    a. Running public campaigns to encourage people to report birds found dead
    b. Financial incentives to report abortion cases
    c. EU requirement to collect a certain number of samples (e.g. avian influenza in wild birds, classical swine fever in wild boar)
3. “Health-event” surveillance: If legislation defines a specific health event leading to mandatory case reporting (e.g. repeated antibiotic failure in pigs for classical swine fever; late abortions for *Brucella* spp.).

It was further agreed that abattoir surveillance shall be termed active if a surveillance protocol exists targeting certain hazards (e.g. bTB). Furthermore, it was agreed if wildlife is captured (wild birds), hunted (e.g. foxes) or trapped (e.g. wild boar, rodents), it shall be termed active if a surveillance protocol considers collection of samples from these animals and passive if no such protocol exists. Surveillance targeting wildlife found dead, sick or involved in accidents shall be termed passive (unless there are enhancements as described above, in which case it would be termed enhanced passive).

Surveillance purpose:

The assignment of a component to a surveillance purpose varied between countries and between hazards within countries. The following aspects were proposed to be considered as decision criteria at various stages of the discussion: Mitigation objective, hazard situation, probability of disease occurrence, policy objective, trade requirements, coverage (comprehensive vs. sample-based), surveillance approach (passive, risk-based active or non-risk-based active). It was agreed that the surveillance purpose should be assigned based on the intended use of the information provided by decision makers. The design of the surveillance approach and its evaluation will in turn depend on the information required by decision makers.

The categories for the surveillance purpose were

> ***1**: Early detection/warning*
>
> ***2**: Substantiate freedom from disease or infection;*
>
> ***3**: Describe baseline disease level, distribution and/or impact of disease;*
>
> ***4**: Describe changes in the health of the population;*
>
> ***5**: Describe changes that may threaten the health of the population;*
>
> ***6**: Detect cases to allow specific action to be taken in animals or holdings which will facilitate control or eradication.*

Since the surveillance purpose was not consistently stated in the documentation of surveillance systems, the following recommendations were agreed on for assigning surveillance purpose:

- If the decision maker's intention / mitigation objective is clear, the purpose shall be stated accordingly;
- If the decision maker's intention is not clear, then the surveillance purpose is determined based on decision criteria outlined in Table 3.

The criteria used to assign the surveillance purpose were also used to assign the associated mitigation stage.

Table 3. Criteria to be used to determine the primary and secondary surveillance purpose and the associated mitigation stages (see Häsler, et al., 2011).

Criteria used to assign surveillance purpose			Surveillance purpose to be assigned		Associated mitigation stage
Hazard situation	Use of information by decision makers criterion 1	Use of information by decision makers criterion 2	Primary surveillance purpose	Possible secondary surveillance purpose	
Present	Aim is to control	Information used to inform control decisions but no specific control action taken following detection	3, 4 or 5	3, 4 or 5	Investigation
		Surveillance	6	3, 4 or 5	Implementation
Present / endemic	Aim is to eradicate	Early phase	6	4	Sustainment
Present / sporadic	Aim is to eradicate	Late phase	1	2	Sustainment
Recent outbreak	Aim is to eradicate	Early phase	6		Sustainment
		Late phase	1	2	Sustainment
Absent	Main use of information is to inform trade requirement	-	2	1	Sustainment
	Not primarily aimed at informing trade requirement	-	1	2	Sustainment
Unknown	Hazard expected to be absent	Relevant for trade	2	1	Sustainment
		Not relevant for trade	1	2	Sustainment
	Hazard expected to be present		3	6	Investigation or implementation

***1**: Early detection/warning; **2**: Substantiate freedom from disease or infection; **3**: Describe baseline disease level, distribution and/or impact of disease; **4**: Describe changes in the health of the population; **5**: Describe changes that may threaten the health of the population; **6**: Detect cases to allow specific action to be taken in animals or holdings which will facilitate control or eradication.*

Risk-based sampling:

In a recently published surveillance terminology paper it was stated that the terms proposed under "the category 'risk-based surveillance' will benefit from further discussion as methods are refined and field applications are reviewed" (Hoinville, et al., 2013). As a result of consistency checks, it was suggested that risk-based sampling could be classified by whether it was based on the risk of infection, consequences or detection. Furthermore, the stage at which the selection of the population was made could be distinguished:

- Step 1: Refers to the selection of the study population on the basis of risk (i.e. species, sector or population stream) and
- Step 2: Refers to the selection of units within this population based on risk (e.g. due to location, type of flock, age of animals).

Examples for risk factors and their categorization as risk of infection, consequences and detection as well as step 1 and step 2 were provided as follows:

- Enhanced passive surveillance of wild bird for HP AI: Geographic area (infection, step 2), preferential sampling of certain species (infection, step 2)
- Active surveillance for BVD in SE: Herd size (infection, step 2), geographic area (infection, step 2), out-degree movements (consequence, step 2)

- Active surveillance of cattle for bTB: Age (detection, step 1)
- Monitoring for salmonella in breeder turkeys – official controls: Breeders being on top of the productive pyramid (consequences, step 1), herd size (infection, step 2)

For the mapping both steps were initially termed risk-based (Table 4) and an additional field created to describe the nature of the risk-based surveillance. Subsequently, three researchers from FLI, SVA and UCM categorized risk-based components into infection/consequence/detection and step 1 or step 2 afterwards to ensure a consistent application of this new terminology and confirm whether the proposed categorization into step 1 and step 2 is useful.

Table 4. Criteria, which justify the categorization of a component as risk-based (RB) in the mapping.

Criteria	Category	To be termed RB
The study population is selected on the basis of risk (i.e. species, sector or population stream)	-	Yes
Units within this population are selected based on risk (e.g. due to location, type of flock, age of animals)	-	Yes
Risk refers to	Infection	Yes
	Consequences	Yes
	Detection	Yes
The population poses a risk of human infection (e.g. slaughter population)		**No,** in the review this will be considered RB prioritization

No agreement was reached on two aspects, which need to be further discussed:

1. Whether passive surveillance can be risk-based;
2. Whether the term risk-based should be applied when the population under surveillance is based on **technical aspects (**e.g. limitation due to test characteristics) and not on **risk** (e.g. testing of older animals for bTB or BSE).

Regarding point 1: AHVLA, RVC and SVA agreed in principle that passive surveillance should not be termed risk-based. Justification against passive surveillance being risk-based was that the entire population is included with no “active assessment of risk involved” and no decision is made on “efficient resource use”. The other view is that sick and dead animals (e.g. for rabies) are selected for testing which means that these animals have a higher risk of infection and therefore resources are used more efficiently by focusing on those population strata (Cliquet, et al., 2010). For example, passive rabies surveillance of indicator animals was termed risk-based in the report by European Commission (2013).

Multi-objective surveillance:

It was agreed to list hazards of multi-objective surveillance components individually so that these hazards could be documented in the report. The field “Description of multi-objective nature” was consequently changed from the yes/no format to a categorical variable with four options: “Multiple”, “Mother”, “Child” and “Not multi-objective” to distinguish between components where:

a) The same samples are tested for multiple hazards (Multiple) or
b) The samples of a Mother component (the primary purpose for sampling), referring to the hazard for which the samples were collected, are used to test for other hazards (Child component or additional usage for further tests).

The information which components are linked as multi-objective, shall be provided in the field “Details multi-objective nature” (e.g. write “Samples are also tested for …” or “Samples from the PRRS surveillance are used”).

Other aspects discussed:

Follow-up and trade-related testing:

It was decided not to consider follow-up investigations as separate components for the mapping as they are the consequence of another component (e.g. abattoir surveillance, passive surveillance).

Furthermore, tests on (groups of) traded animals for intra-Community (i-C) trade (to another EU MS) or extra-Community (e-C) trade (i.e. Third Country trade) were also not listed as separate components because[1]:

- Whilst i-C trade is regulated, requirements for e-C trade depend on demands of trading partners (i.e. importers). Given the hazard-specific breakdown of components, including e-C trade may add large number of components, which cannot be distinguished from surveillance based on legal requirements or private initiatives. This was expected to distort the general picture given the equal weighting of components.
- However, it is recognized that export testing may contribute to the overall surveillance as auxiliary information. Therefore, two sections will be included in text form in the mapping report:
    - I-C trade: Hazard-specific regulations for i-C trade and the countries affected by those regulations will be summarized. The number of animals traded within the EU for this country can be derived from Appendix C of the mapping report (trade flows).
    - E-C trade: Main trading partners (and requirements) and number of animals traded per species will be summarized for individual countries to indicate the amount of export testing done in 2011.

Health event, event related and follow-up test: It was decided to separate the term “event-related” (e.g. prior to movements) (Hoinville, et al., 2013) from “health event” surveillance. The term “health event surveillance” was used if legislation defines a health event (e.g. abortion, neurological symptoms, repeated antibiotic failure) that leads to mandatory notification of authorities. The different term was proposed as the underlying concepts for “event-related” and “health-related” surveillance differ.

Case definitions: It was suggested that in future data collections it would be useful to distinguish between screening and confirmatory tests when assessing the case definition.

True versus official freedom (according to the OIE): The need to distinguish between true and official freedom was emphasized. It was decided to determine the surveillance purpose of the mapping based on official freedom and the hazard situation of the review based on true freedom.

4.2 Review

Consortium members agreed that additional data needed to be collected to fulfill the objectives of the review of surveillance systems, that is to detect variation in legislation and describe basic epidemiological characteristics of current surveillance systems (see Section 3). The FLI group coordinated discussions of the data requirements with partners involved in data collection for the review and key representatives of WPs 1 and 5 in order to develop a protocol. This included,

- Preparation of a first variable list based on suggestions by WP 2 (AHVLA and UCM) including a description of the variables, data types and possible categories,
- Development of guiding emails or documents for the follow-up discussion;

[1] Please note that export testing only refers to (groups of) traded animals. If there is a requirement to test the general population (not just the specific animals to be exported), then this should be listed.

- Set up and coordination of exchanges between WPs 1 to 5 per email or Skype (three meetings in M4, M5 and M8); and
- Incorporation of comments and suggestions into the emerging documents.

The discussions were not only related to data requirements (type, level of detail, data structure), but also to the underlying conditions for data collection (countries, hazards, standardization of data collection and validation). Given the high workload gathering even the mapping data, human resources for this project were an ongoing concern.

A final variable list of agreed data requirements was finalized on 18 September and incorporated into an Access database by RVC on 30 September. After pilot testing, the final database was sent on 14 October. However, since the consistency checks resulted in further adjustments, it was recommended to validate the mapping database first and then use this database as the template for the review database (after 22 November). Data entry is planned to be finished by mid-January.

Following the experience from the mapping, it will be crucial to carry out consistency checks for the review as well. But given agreements on major issues such as component splitting, it is expected that people are more aware of potential problems arising from differing interpretations and will contact other partners more readily when encountering unclear aspects. A Skype discussion is organized in December and a general consistency check shall be performed on the entire review data set in mid-January to ensure consistency of the review data.

4.3 Questionnaire to document data collection on surveillance systems in partner countries

During the initial data collection (leading to the “initial data set”), Countries 4, 5 and 6 involved five to seven staff members, whilst the other countries involved one to three staff members. In contrast, only one or two staff members were only involved (Country 2: three staff members) when the initial data set was validated during consistency checks.

In total, 164 people were contacted by consortium staff members to get additional information on surveillance systems. Of these people, 55.5% were contacted by email, 28% by phone and 16.5% in a personal meeting (each person was only counted in the column indicating the highest level of interaction, i.e. personal meeting > phone > email). Country 6 contacted most people (n = 99), followed by Countries 5 (n = 26), 2 (n = 22) and 1 (n = 7) (Figure 5). The other countries contacted up to five people. Most contacts were from the public sector. Contacts from the private sector or with academic background were only contacted by three and two countries, respectively.

Publicly accessible resources on the existence, design and results of surveillance systems were in general better documented for public than for private surveillance systems (Figure 6). However, the design and expenditure of public surveillance systems also had a relatively low rank (median rank of 3 and 2, respectively. Considerable variations existed to what extent regional differences existed in the design of surveillance systems. Whilst Countries 2 and 7 ranked regional design differences as highly applicable, Countries 4, 5 and 6 ranked this statement as not applicable. Variations also existed in the assessment of the contacts’ concerns about confidentiality, clarity of instructions, interest and preparedness to contribute.

The rank of the confidence of understanding definitions and instructions tended to increase from a median rank of three to a median rank of four (Figure 7a). The estimated completeness of the components was highest for national public components and lowest for regional private components (Figure 7b). Considerable variability existed in the estimated completeness of national private and regional public components.

5 Discussion

The application of consistent terminology is crucial to ensure robust data quality and facilitate comparisons between surveillance systems. In recent years, efforts have been made to standardize terminology for animal health surveillance based on the outcome of a pre-ICAHS workshop in 2011 involving renowned surveillance experts (Hoinville, 2013, Hoinville, et al., 2013). The data collection for the mapping and review provided a valuable opportunity to pilot test these definitions. Consistency checks of data collected for the mapping demonstrated differences in interpretation of terminology, which affected validity of results presented in the draft mapping report. Since consortium members collecting the data can be considered experts in epidemiology and animal health surveillance, people with less expertise would have had at least similar problems in applying the definitions in a consistent manner. The aims of this report were to describe the final design of the mapping and review tasks, describe problem areas identified during consistency checks of the mapping data, document recommendations to improve consistency and discuss current limitations in the documentation of surveillance systems.

5.1 Data collection for the mapping

The workload of collecting information on existing surveillance systems exceeded by far the expectations of consortium members. Several reasons exist for the high workload related to the data collection:

First, in most countries, no centralized system exists that documents details about and results of surveillance system activities. Consequently, a multitude of sources, such as the internet, government reports, scientific literature, etc. needed to be consulted to cover a wealth of hazards and surveillance variables defined in the mapping data collection protocol. The degree of documentation, availability of alternative sources (e.g. personal contacts) and efforts made to seek additional information may have varied between countries. Hence, two sources of bias may have occurred (Grimes, et al., 2002, Barratt, et al., 2009):

1) Selection bias as public components are generally better documented than private surveillance components
2) Observer bias as researchers may have chosen different approaches to collect the data

Selection bias could be reduced by centralizing registrations of surveillance efforts to allow an overview and better coordination of efforts made by the public and private sector. Criteria and a minimum set of variables could be defined for such a purpose. This would facilitate better documentation of surveillance (e.g. when demonstrating disease freedom), indicate opportunities to coordinate efforts and allow better comparison of surveillance activities. Implementation of such a centralized database is not within the scope of the RISKSUR project, but is presented as a suggestion for policy makers to facilitate analysis of a country's surveillance systems.

To reduce observer bias in the review, a standard protocol was developed outlining a sequence of steps that should be followed when searching for information. However, given the variety of options how information can be accessed for different countries, hazards and sectors, this standard protocol was not strictly followed, so that observer bias may still be an issue for the review. Promoting a common understanding of the protocol developed as well as strict adherence to the protocol can reduce observer bias to a minimum, but not completely remove it.

Due to the selection and observer bias, the data can only be used to obtain insight into the variability between countries, but should not be used for specific comparisons of countries.

Secondly, when a surveillance system was identified, data for specific variables were often not available. Especially, hard facts such as expenditures and surveillance results are not routinely reported. But also design aspects such as surveillance purpose and sampling strategies are often not documented. It is recommended to propose a minimum set of variables when documenting surveillance systems to achieve a

standard description and thus facilitate comparability. During the course of the project, a list of valuable variables should be developed and further revised in the light of ongoing research outputs by WPs 2-5. It is recommended to seek external input at an early stage to develop a universally applicable terminology.

Thirdly, devolution of responsibilities to different administrative units (i.e. decentralization) varies between countries in the EU. Whilst some countries have a strongly centralized system (e.g. NL, SE, UK), others are strongly decentralized (e.g. DE, ES, FR). Surveillance efforts in decentralized countries may be more variable, thus making it difficult to document them in the form of a single component at the national level, and are often not well documented. Hence, the degree of regionalization affects the time to collect data, accuracy and completeness of components (confounding bias).

Lastly, confidentiality was raised as a concern by some countries. In some instances, people did not agree to share data at all or not if they are shared with other countries. The high level of aggregation used for the mapping, the anonymization of countries and the fact that only the report but not the raw data will be transferred to DG Research were useful arguments to encourage people to share their data. Furthermore, the scientific and professional advisory boards created as part of the project to ensure the scientific quality, impact and relevance of RISKSUR outputs were asked for advice on how to present the results. One lesson of the mapping was that surveillance is a sensitive topic, so that it is crucial to clearly explain to contributing parties the purpose and expected outcome of the data collection.

In conclusions, data collection for the mapping exercise has demonstrated limitations in how surveillance systems are documented, potential sources of bias when doing a multi-country assessment and the need to involve decision- and policy makers in such an activity to gain their approval and preparedness to cooperate.

5.2 Consistency checks

Data collection for the mapping provided a useful pilot test of the surveillance definitions. The validation of the initial data set submitted in June through consistency checks demonstrated various important aspects that were either not clearly understood or differently interpreted such as component splitting, means of data acquisition, risk-based sampling, surveillance objective/purpose and multi-objective surveillance. Most aspects were agreed on after in-depths discussions. But several aspects require further discussions.

First, for enhanced passive surveillance further discussion is required about whether the criteria presented in this report can be generally used to define such a system. Secondly, the distinction of the surveillance purposes “early detection” and “disease freedom” is not solved. A drawback with criteria in **Fehler! erweisquelle konnte nicht gefunden werden.** is that early detection and disease freedom always occur in combination either as primary or secondary purpose. Surveillance activities carried out when diseases are absent are often used both to demonstrate disease freedom and for early detection. For data collection, it was decided to choose disease freedom as primary purpose whenever the information shall be used to inform a trade requirement. However, profound differences may exist in surveillance design between “disease freedom” and “early detection” such as whether risk of consequences is considered or not (Cameron, 2012), how frequently surveillance is performed (e.g. an annual survey may not be suitable for early detection) and what the population coverage is. In fact, different components of the same hazard could have different surveillance purposes. Therefore, it is important to be clear about the primary purpose of any surveillance activity because it determines the design of surveillance. Clarification of how to define the surveillance purpose and its relation to the design of surveillance need to be further developed. Thirdly, terminology related to risk-based surveillance needs to be discussed further (Hoinville, et al., 2013). It would be a useful output of the RISKSUR project to elaborate on terminology, and hence to promote a common understanding and robust documentation of surveillance activities.

The outcomes of this ongoing task of refining terminology could be documented in form of a field manual with simple elaborations and practical examples. The surveillance terminology presented by Hoinville, et al. (2013) formed the basis for definitions used in this project, so that this terminology can be adapted and

adjusted if problems of understanding are encountered. The mapping and review have identified plentiful examples which could be used to supplement definitions in an illustrative manner. The development of a standard manual would be a major project output, but would require input not just from consortium members but also from external experts.

Input from external experts could be obtained in various ways. Two options are proposed to facilitate external input and comments:

1. The RISKSUR website could be used to document extended/revised definitions supplemented with examples. In the RISKSUR newsletter, people could be encouraged to look at and comment on these proposals in blog comment areas. This would allow incorporation of alternative views at an early stage.
2. At the end of Year 2 of the project, a survey could be performed targeting people involved in surveillance of various sectors. This survey could assess whether people clearly understand the proposed standard definitions, have alternative views and would be prepared to register a minimum set of information in a central database.

Based on that feedback, a field manual could then be developed in Year 3 incorporating recommendations of the project.

5.3 Outlook

The following issues covered in this report will be developed further as part of the project and communicated to the scientific community with the aim to standardize definitions and documentation efforts:

- Determinants of a component in relation to data source and data collection method;
- Criteria justifying the categorization of a component as “Enhanced passive surveillance”;
- Decision criteria assigning surveillance purpose;
- Risk-based surveillance: How to distinguish different types of risk-based sampling, whether to consider the risk of consequences when designing surveillance for different purposes, how to classify surveillance that is based on the risk of detection due to limitations in diagnostic test;
- Whether passive surveillance can be risk-based;
- Better definition of survey versus continuous data collection;
- Separation of health-event, event-related and follow-up tests;
- Further clarification of terms not widely applied during data collection (e.g. sentinel surveillance, media-based surveillance);
- Potentially development and pilot testing of a surveillance manual that may serve as a general standard to document surveillance at least across the EU.

6 Conclusions

The mapping data collection and subsequent consistency checks were crucial elements of the early part of the RISKSUR project as it highlighted limitations in how surveillance is documented and in surveillance terminology. This report documents suggested refinements of terminology, discussed issues related to data collection in the field and related biases and contains a set of recommendations. Further efforts should be made to refine definitions and guidelines related to surveillance terminology, in particular to risk-based surveillance. It is recommended to develop a draft manual and validate it in cooperation with a range of external experts.

7 Appendix

7.1 Hazards covered

Table 5. Shortlist of hazards considered for selection of case studies used for the review of surveillance systems.

No.	Hazard	Relevant for		
		WP 2 (Early detection)	WP 3 (Disease freedom)	WP 4 (Endemic disease)
1	A potential emerging disease*	X		
2	Aujesky's disease	X	X	
3	Avian influenza - highly Pathogenic	X	X	
4	Avian influenza - low Pathogenicity (H5 and H7)	X	X	
5	BHV-1		X	X
6	Bluetongue	X	X	X
7	Bovine neonatal pancytopaenia	X		X
8	Bovine tuberculosis	X	X	X
9	Brucella abortus	X	X	X
10	Brucella melitensis	X	X	X
11	BSE		X	X
12	BVDV		X	X
13	Classical swine fever	X	X	
14	Equine infectious anaemia	X		
15	Equine viral arteritis	X		
16	Foot and mouth disease	X	X	
17	Footrot			X
18	Maedi/Visna			X
19	Newcastle disease	X	X	
20	Paratuberculosis		X	X
21	PRRS			X
22	Q-Fever			X
23	Salmonella			X
24	Schmallenberg[2]	X		X
25	Scrapie		X	X
26	West Nile virus	X	X	
Hazards excluded from the initial list of potential case study hazards as of 19 July 2013				
27	African horse sickness			
28	African swine fever			
29	Contagious equine metritis			
30	Crimean Congo haemorrhagic fever			
31	Nipah virus			
32	PMWS			
33	Rabies			
34	Rift Valley fever			
35	Swine vesicular disease			

7.2 Variables covered

7.2.1 Mapping

Table 6. Information to collect for the mapping of surveillance systems.

[2] Not relevant for the Review as no surveillance has been carried out in 2011.

FIELD		FIELD NUMBERS and TYPES	Description and/or comments
A. ID		Field A.1: ID automatically attributed	Automatic
	OLD	Field A.1: ID from old databases	Locked
B. Country ID	**OLD**	Field B.1: Country ID from old database	Previous entry.
		Field B.2: Free text DE: Germany, SE: Sweden, ES: Spain FR: France…	To be entered by data collectors.
C. Threat or disease focus or health event	**OLD**	Field C.1: Data previously entered and to be updated or corrected if applicable in C.2/C.3	Locked
		Field C.2: Check box list: ☐ Antimicrobial resistance ☐ Avian influenza ☐ Bluetongue ☐ Brucella ☐ BSE ☐ Emerging diseases ☐ Mastitis ☐ Paratuberculosis ☐ Rabies Etc.	based on previous entries.
		Field C.3: Separate "other" field, free text	
D. Surveillance component	**OLD**	Field D.1: Data previously entered and to be updated or corrected if applicable in D.2	Locked
		Field D.2: free text	To be filled in by data collectors
E. Target species	**OLD**	Field E.1: Data previously entered to be used as basis and to be updated or corrected if applicable in E.2	Locked
		Field E.2: Check box list: ☐ Cattle ☐ Pig ☐ Horse ☐ Donkey ☐ Sheep ☐ Goat ☐ Turkey ☐ Chicken ☐ Duck ☐ Birds (non-poultry) Etc	Multiple entries can be selected here. If "other" please specifiy in E.3
		Field E.3: Separate "other" field, free text	To account for items not in the check box list.
F. Target sector		Field F.1: Check box list list ☐ Dairy ☐ Beef ☐ Layer ☐ Broiler ☐ Breeder ☐ Finisher etc	List based on the old mapping data and the document TypeEntries.doc.
		Field F.2: Separate "other" field, free text	To account for items not listed above
G. Target type	**OLD**	Field G.1: Data previously entered and to be updated or corrected if applicable in G.2 and G.3	Locked
		Field G.2: A check box list with target type ☐ Young male ☐ Adult male ☐ Young female ☐ Adult female ☐ Breeding male ☐ Breeding female Etc	List based on the mapping data and the document TypeEntries.doc
		Field G.3: Separate "other" field, free text	To account for items not listed above
H. Target criteria	**OLD**	Field H.1: Data previously entered. To be updated or corrected if applicable in H.2	Locked

FIELD		FIELD NUMBERS and TYPES	Description and/or comments
		Field H.2: Free text	To be completed by data collectors, will contain any other criteria used to define the target population (e.g. >24 months old, found dead, etc.)
I. Sampling point		Field I.1: A dropdown : □ Abattoir □ Insemination centre □ Farm □ Milk collection centre □ Egg collection centre □ Processing plant □ Transporter □ Trader □ Retailer Etc	List created based on mapping data.
		Field I.2: Separate "other" field, free text	To account for items not listed above
J. Geographical focus	**OLD**	Field J.1: Data previously entered. To be updated or corrected if applicable in J.2	Locked
		Field J.2: Check box list □ Local □ National □ Regional □ Unknown	Same list as before
		Field J.3: Separate "other" field, free text	To account for items not listed above
K. Overarching programme or organisation	**OLD**	Field K.1: Data previously entered. To be updated or corrected if applicable in K.2	Locked
		Field K.2: free text	To be described by data collectors
L. Primary purpose	**OLD**	Field L.1: Data previously entered. To be updated or corrected if applicable in L.2	Locked
		Field L.2: Drop down list ○ Early detection/ warning ○ Substantiate freedom from disease or infection ○ Describe baseline disease level, distribution and/or impact of disease ○ Describe changes in the health of the population ○ Describe changes that may threaten the health of the population ○ Detect cases to allow specific action to be taken in animals or holdings which will facilitate control or eradication ○ Unknown	
		Field L.3: Separate "other" field, free text	Same list as before, but drop down instead of check box list.
M. Secondary purpose	**OLD**	Field M.1: Data previously entered. To be updated or corrected if applicable in M.2	Locked

FIELD		FIELD NUMBERS and TYPES	Description and/or comments
		Field M.2: Drop down list ○ Early detection/ warning ○ Substantiate freedom from disease or infection ○ Describe baseline disease level, distribution and/or impact of disease ○ Describe changes in the health of the population ○ Describe changes that may threaten the health of the population ○ Detect cases to allow specific action to be taken in animals or holdings which will facilitate control or eradication ○ Unknown	
		Field M.3: Separate "other" field, free text	
N. EU legal obligation, national legal obligation, private initiative regulations	**OLD**	Field N.1: Data previously entered. To be updated or corrected if applicable in N.2	Locked
		Field N.2.: Drop down list: ○ EU and National legal obligation ○ EU and National legal obligation PLUS private regulation ○ EU legal obligation ○ EU legal obligation PLUS private regulation ○ National legal obligation ○ National legal obligation PLUS private regulation ○ None ○ Private initiative regulation ○ Unknown ○ Voluntary Etc	Entries based on cleaned database from previous entry
		Field N.3: Separate "other" field, free text	To account for items not listed above
O. Component managed privately, publicly or both	**OLD**	Field O.1: Data previously entered. To be updated or corrected if applicable in O.2	Locked
		Field O.2: A drop down list: ○ Privately ○ Publicly ○ Both ○ Unknown	As before
P. Total expenditures for component [in EUR]	**OLD**	Field P.1: Data previously entered. To be updated or corrected if applicable in P.2	Locked
		Field P.2: Numeric field, free entry	As before, but numeric.
Q. Percentage of total expenditures covered by public funding [%]	**OLD**	Field Q.1: Data previously entered. To be updated or corrected if applicable in Q.2	Locked
		Field Q.2: Drop down list: ○ >Private ○ >Public ○ 100% private ○ 100% public ○ 50:50.	Categories based on previously entered data.
R. Private share of the surveillance component funded by	**OLD**	Field R.1: Data previously entered. To be updated or corrected if applicable in R.2	Locked
		Field R.2: A check box list ☐ Industry ☐ Animal disease fund ☐ Individuals (e.g. farmers or owners) Etc	Categories based on previously entered data.
		Field R.3: Separate "other" field, free text	To account for items not listed above
S. Short description	**OLD**	Field S.1: Data previously entered. To be updated or corrected if applicable in S.2	Locked
		Field S.2: free text	To be completed by data collectors
T. Means of data	**OLD**	Field T.1: Data previously entered. To be updated or corrected if applicable in T.2	Locked

FIELD		FIELD NUMBERS and TYPES	Description and/or comments
acquisition		Field T.2: A drop down list ○ Active ○ Passive ○ Enhanced passive ○ Unknown	Same list as before
U. Study design	OLD	Field U.1: Data previously entered. To be updated or corrected if applicable in U.2	Locked
		Field U.2: A dropdown list ☐ Voluntary case reporting ☐ Mandatory case reporting ☐ Survey ☐ Continuous data collection ☐ Participatory ☐ Sentinel ☐ Event-based (media-based) ☐ Unknown ☐ Other (please specify in next column)	Same list as before
		Field U.3: Separate "other" field, free text	To account for items not listed above
V. Case definition	OLD	Field V.1: Data previously entered. To be updated or corrected if applicable in V.2	Locked
		Field V.2: A check box list ☐ Clinical signs or syndrome ☐ Indirect indicators (drug sales, abattoir submissions, …) ☐ Gross pathology ☐ Laboratory test for pathogens or toxins ☐ Laboratory test for host response ☐ Specified diagnostic criteria ☐ Risk factor(s) ☐ Unknown	Same list as before
		Field V.3: Separate "other" field, free text	To account for items not listed above
		Field V.4: Comments field, to give more details on choice of V2	
W. Risk-based sampling	OLD	Field W.1: Data previously entered. To be updated or corrected if applicable in W.2	Locked
		Field W.2: A drop down list: ○ No ○ Yes ○ Unknown	Same list as before
		Field W.3: text field where the risk factors that led to the categoristation of the component above as "RB sampling" shall be entered	
X. Description of multi-objective nature	OLD		Locked
		Field X.2: A drop down list: ○ Multiple (please specify in next column) ○ Mother ○ Child ○ Not multiobjective ○ Unknown	New list based on recommendations from consistency checks
		Field X.3: Please give details if multi-objective, free text field	Separate field to specify the details, if multi-objective
Y. Reference(s)/source(s)	OLD	Field Y.1: Data previously entered. To be updated or corrected if applicable in Y.2	Locked
		Field Y.2: Free text field	To be completed by data collectors
Z. Comments	OLD	Field Z.1: Data previously entered. To be updated or corrected if applicable in Z.2	Locked
		Field Z.2: Free text field	To be completed by data collectors

7.2.2 Review

Table 7. Information to collect for the review of surveillance systems. The review data are added to the mapping data, so that the variables of Table 6 are also included in the review.

No.	FIELD	FIELD TYPE	Description and/or comments
1	Work package	A check box list ☐ WP2 (Early detection) ☐ WP3 (Disease freedom) ☐ WP4 (Endemic diseases) ☐ None ☐ Unknown	To which work package(s) does this component relate to? (*tick one or more*)
2	Hazard situation	A drop down list: ○ Endemic ○ Sporadic ○ Free ○ Exotic ○ Re-emerging ○ New ○ Situation varies, please specify ○ Unknown	What was the situation of the hazard in the country / region in 2011? (*tick one)*
		Separate ”other” field, free text	To account for items not listed above
3	Participation	A drop down list: ○ Voluntary ○ Mandatory ○ Not applicable ○ Unknown	Specify if participation was voluntary or mandatory. (*tick one)*
4	Observational unit	A drop down list: ○ Indiv. Animal ○ Herd/flock ○ Pen / house ○ Other, please specify ○ Not applicable ○ Unknown	What was the observational unit? (*tick one)*
		Separate ”other” field, free text	To account for items not listed above
5	RB surveillance approach(es)	A check box list ☐ No RB surveillance ☐ RB prioritisation ☐ RB requirement ☐ RB sampling ☐ RB analysis ☐ Not applicable ☐ Unknown	What surveillance approach(es) was/were used? (*tick one or more*)
6	Risk factors	A check box list ☐ Geography, please specify ☐ Animal factors, please specify ☐ Management factors, please specify ☐ Environmental factors, please specify ☐ Other factors, please specify ☐ Not applicable ☐ Unknown	What risk factor(s) was/were used? (*tick one or more*)
		Separate ”Geography” field, free text	Specify if ”geography” selected
		Separate ”Animal factors” field, free text	Specify if ”animal factors” selected
		Separate ”Management factors” field, free text	Specify if ”management factors” selected
		Separate ”Environmental factors” field, free text	Specify if ”environmental factors” selected
		Separate ”Other factors” field, free text	Specify if ”other factors” selected
7	Risk factor assessment	A drop down list: ○ Quantitative ○ Semiquantitative ○ Qualitative ○ Literature information ○ Expert opinion ○ Other, please specify ○ Not applicable ○ Unknown	What methods were used to assess these risk factors? (*tick one)*
		Separate ”other” field, free text	To account for items not listed above

No.	FIELD	FIELD TYPE	Description and/or comments
8	Requirement	A drop down list: o Input-based o Output-based o Optional o Not applicable o Unknown	Were legal requirements input- or output-based?
9	Herd design prevalence	Decimal field with two decimal places (range: -997; -998; 0.01 to 100) If " not applicable" please do enter "-997" here If "unknown" please do enter "-998" here	What was the (between) herd design prevalence (%)?
10	Animal design prevalence	Decimal field (range: 0.01 to 100; -997 or -998)	What was the animal (within herd) design prevalence (%)? Enter -997 if not applicable and -998 if unknown
11	Confidence level	Decimal field (range: 0.01 to 100; -997 or -998)	What was the specified confidence level (%)? Enter -997 if not applicable and -998 if unknown
12	Selection method	A check box list ☐ Census ☐ Convenient ☐ Purposeful ☐ Simple random ☐ Systematic random ☐ Stratified random ☐ Multistage random ☐ Other or combination, please specify ☐ Not applicable ☐ Unknown	How were units selected? (*tick one or more*)
		Separate "other" field, free text	To account for items not listed above
13	Sample type(s)	A check box list ☐ Blood / plasma / serum ☐ Animal swab ☐ Tissue ☐ Carcass ☐ Faeces ☐ Urine ☐ Semen ☐ Milk / colostrum ☐ Environmental sample ☐ Clinical surveillance ☐ Post-mortem ☐ Other, please specify ☐ Not applicable ☐ Unknown	What sample type(s) was/were collected? (*tick one or more*)
		Separate "other" field, free text	To account for items not listed above
14A	Cat No of units in target population	A drop down list: o If national population assessed in mapping; please enter "0" here o Other population, please specify o Not applicable o Unknown	How many units (e.g. farms) did the target population comprise in 2011?
14B	No of units (eg farms) in target population	Numeric: Value of either count or percentage selected in 16A; enter positive number, -998 or -997	Enter the number of units (e.g. farms) of the targeted population in 2011; enter -997 if not applicable and -998 if unknown
15A	Cat No of animals in target population	A drop down list: o If national population assessed in mapping; please enter "0" here o Other population, please specify in next field o Not applicable o Unknown	How many animals did the target population comprise in 2011?
15B	No of animals in target population	Numeric value	Enter the number of animals of the targeted population in 2011; enter -997 if not applicable and -998 if unknown
16A	No/% of units required to be investigated	A drop down list: o As count, please enter value o As percentage (%), please enter value o Not applicable o Unknown	Total number or percentage of units (e.g. farms) that should have been investigated in 2011
16B	No/% of units required specified	Numeric: Value of either count or percentage selected in 16A; enter positive number, -998 or -997	Value of either count or percentage selected in 16A

No.	FIELD	FIELD TYPE	Description and/or comments
17A	No/% of animals required to be investigated	A drop down list: o As count, please enter value o As percentage (%), please enter value o Not applicable o Unknown	Total number or percentage of animals that should have been investigated in 2011
17B	No/% of animals required specified	Numeric: Value of either count or percentage selected in 17A	Value of either count or percentage selected in 17A
18	No. of samples required to be collected	Positive integer, -998 or -997	Total number of samples that should have been collected in 2011; enter -997 if not applicable and -998 if unknown
19	No. of units (e.g. farms) actually investigated	Positive integer, -998 or -997	Total number of units (e.g. farms) that were investigated in 2011; enter -997 if not applicable and -998 if unknown
20	No. of animals actually investigated	Positive integer, -998 or -997	Total number of animals that were investigated in 2011; enter -997 if not applicable and -998 if unknown
21	No. of samples actually collected	Positive integer, -998 or -997	Total number of samples collected in 2011; enter -997 if not applicable and -998 if unknown
22	Pooling	A drop down list o No o Yes o Not applicable o Unknown	Were samples pooled for any diagnostic method? (*tick one*)
23	Source information	A check box list ☐ Publication ☐ Report ☐ Internet ☐ Personal information from contact ☐ Personal information from other person ☐ Instruction from ministry ☐ Animal disease notification systems ☐ I & R databases ☐ Other	Which source(s) did you use to gather information on this hazard? (*tick one or more*)

7.2.3 Questionnaire to document data collection on surveillance systems in partner countries

Name: _____

Institution: _____

Assigned non-partner country: _____

Note: If you have covered more than one non-partner country, then please fill out the questionnaire twice (the second time only for the 2nd non-partner country).

1. How many people in your institution contributed to the mapping for your country (partner country)?

Time period	Sub-tasks	Own country
Prior to June	Finding source documents	
	Collecting data	
	Entering data	
	reviewing the collected data before submission in June	
October/November	reviewing the adjusted Access database	
	Validating the June DB based on outcomes of consistency checks	
	reviewing the validated DB prior to final submission	

2. Please estimate for the mapping of your country (partner country) the number of people, whom you tried to contact per email, per phone or met in person to get additional information on surveillance systems (subsequently referred to as "contact" in partner countries). Each person should only be counted in one column, that is the column indicating the highest level of interaction (Meeting > phone > email).

Estimated no. of people contacted	Per Email	Per phone	In person
Public institutions (excl. laboratories)			
Public laboratories			
Private associations			
Academic institutes			
Other: Please specify ……..			

3. Please rank on a scale from 1 (not applicable) to 5 (highly applicable) to what extent the following statements are applicable regarding the documentation of surveillance systems in **your country (partner country)**. You can add additional aspects in the empty lines.

Statements: Partner country	Rank	Unknown
A centralized system documenting public surveillance exists		☐
The existence of public surveillance systems is sufficiently documented		☐
Design details of public surveillance systems are sufficiently documented		☐
Results of public surveillance systems are sufficiently documented		☐
Expenditures of public surveillance systems are well documented		☐
The existence of private surveillance systems is sufficiently documented		☐
Design details of private surveillance systems are sufficiently documented		☐
Results of private surveillance systems are sufficiently documented		☐
Expenditures of private surveillance systems are well documented		☐
Regional differences exist in the design of surveillance systems		☐
Contacts were concerned about the confidentiality of data[a]		☐
Contacts[a] were generally happy to contribute information		☐
Contacts[a] generally clearly understood instructions		☐
Contacts[a] were generally interested in the data collection and expected results		☐
Contacts[a] raised concerns about reporting results to the EU		☐
…		☐
…		☐
…		☐

[a]. For partner countries: Contacts can be any persons that were contacted with the aim to gather additional info (not just the official contact person).

4. Please rank on a scale from 1 (not confident) to 5 (very confident) how confident you and the other staff members involved in data collection feel that you clearly understood the instructions and definitions of variables.

Part of instructions	Rank
From the initial instructions (prior to July)	
From the instructions following consistency checks (prior to 22 November)	

5. Please rank the completeness of components in your country (partner country) on a scale from 1 (highly incomplete) to 5 (highly complete).

Component	Rank of completeness	Unknown
Regional public components		☐
Regional private components		☐
National public components		☐
National private components		☐

You can write additional comments here (e.g. future needs when documenting surveillance systems; suggestions for future surveys like this; …):

7.3 Existing definitions

7.3.1 Definition of a surveillance components

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 (Hoinville, 2013)

In the task plan for RISKSUR theme Framework development 130909.docx (p. 3)

Surveillance component: Currently defined within RISKSUR as is a single surveillance activity used to investigate the occurrence of one or more hazards or health events in a specified population, which has a self-contained surveillance protocol that focuses on a particular data source.
The relation between a surveillance component, the epidemiological design and the data generation process (DGP) (see definition below) and is that the former consists of a DGP on to which an epidemiological design may be applied. However, some DGPs may generate information without an epidemiological design being applied to them.

7.3.2 Passive and enhanced passive surveillance

Hoinville (2013)

Passive surveillance: *Observer-initiated provision of animal health related data (e.g. voluntary notification of suspect disease) or the use of existing data for surveillance. Decisions about whether information is provided, and what information is provided from which animals is made by the data provider.*

Enhanced passive surveillance: *Enhanced passive surveillance: Observer-initiated provision of animal health related data with active investigator involvement e.g. by actively encouraging producers to report certain types of disease or by active follow up of suspect disease reports.*

Hoinville, et al. (2013)

Enhanced passive surveillance: *as above, but specified in more detail as follows: The term 'enhanced passive surveillance' arose to describe 'passive' systems or components … that have been fine-tuned by the investigator to standardise and better use the information obtained (Ouagal et al., 2010). 'Enhanced passive' has been used to describe either surveillance systems or their components. 'Enhanced passive' surveillance systems are used to capture trends emerging from otherwise seemingly isolated disease events or syndromes. In isolation, a set of symptoms might be of minimal concern – but awareness that syndromes are co-occurring in multiple locations or data sources might initiate a different level of investigation. Any activities encouraging opportunities either for regional awareness or for assessment of disease events or syndromes may be considered examples of an 'enhanced passive' system. The data collection is driven by the producers and their veterinarians, but the overseeing investigator coordinates the review of veterinary concerns or syndromic findings routinely compiled from multiple locations. Thus, the 'passive' system is enhanced through active oversight.*

- *Encouragements like incentives, awareness campaigns;*
- *Syndromic surveillance*

In contrast to this use of the term 'enhanced passive' to refer to surveillance systems, an 'enhanced passive' surveillance component is a single surveillance activity in which data provision is initiated by the observer but in which the quality of the data provided is improved by the investigator (to enhance its use in surveillance). Examples include regular active encouragement of producers to report certain types of diseases or specification and recording of data so it can be shared easily with surveillance investigators (Ouagal et al., 2010). The investigator requests the type and format of information to be shared; the producer participates by agreeing to share routine health (or riskfactor)

data (on either a pre-set or sporadic basis). 'Active observational surveillance' has been proposed as an alternative term to describe this type of 'enhanced passive' component.

- *Routine submission of health data according to a standard protocol*

7.3.3 Mitigation stages and surveillance purpose

Häsler, et al. (2011):

- In Stage I, 'sustainment', the mitigation objective is to sustain a free or acceptable status by preventing an increase of a pathogen or eliminating it when it occurs. The role of surveillance is to document that the pathogen remains below a defined threshold, giving early warning of an increase in incidence or other significant changes in risk, and enabling early response;
- Stage II, 'investigation', the mitigation objective is to assess the situation and obtain critical epidemiological information to decide on the appropriate intervention strategy to reduce or eradicate a disease;
- In Stage III, 'implementation', surveillance informs the choice, timing, and scale of interventions and documents the progress of interventions directed at prevalence reduction in the population[3].

7.4 Questionnaire results

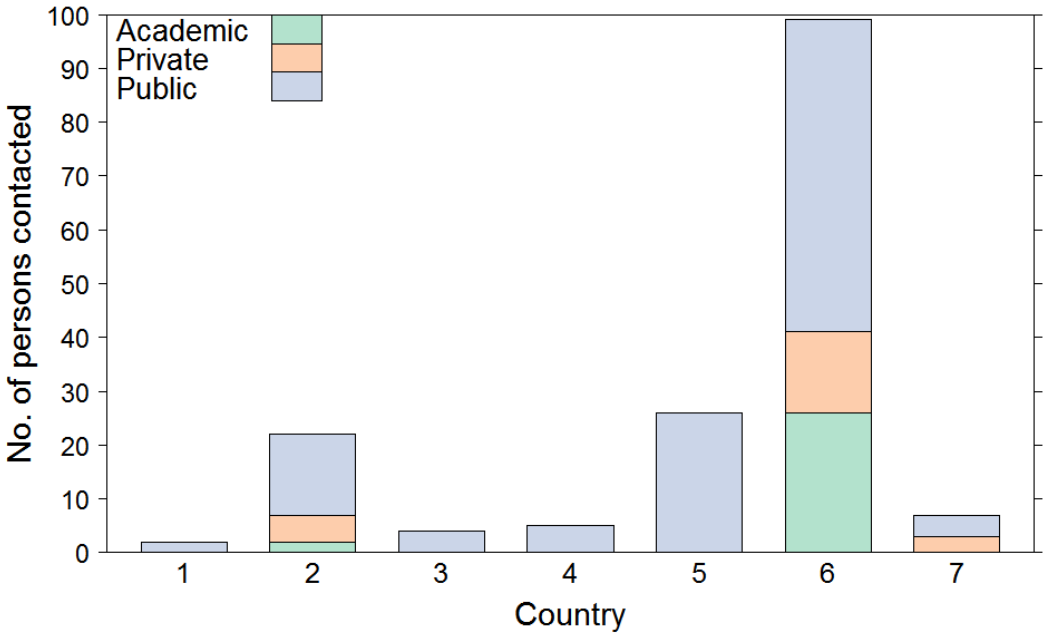

Figure 5. Number of persons of the academic, private or public sectors, which were contacted by partner countries 1 to 7 to get additional information on surveillance systems (*n* = 164).

[3] These mitigation stages apply to a hazard-free situation (stage I) or to situations where the hazard is present regardless of the level (sporadic, endemic, post-epidemic, …) (stages II and III). The focus of stages II and III is either monitoring (stage II) or surveillance (stage III).

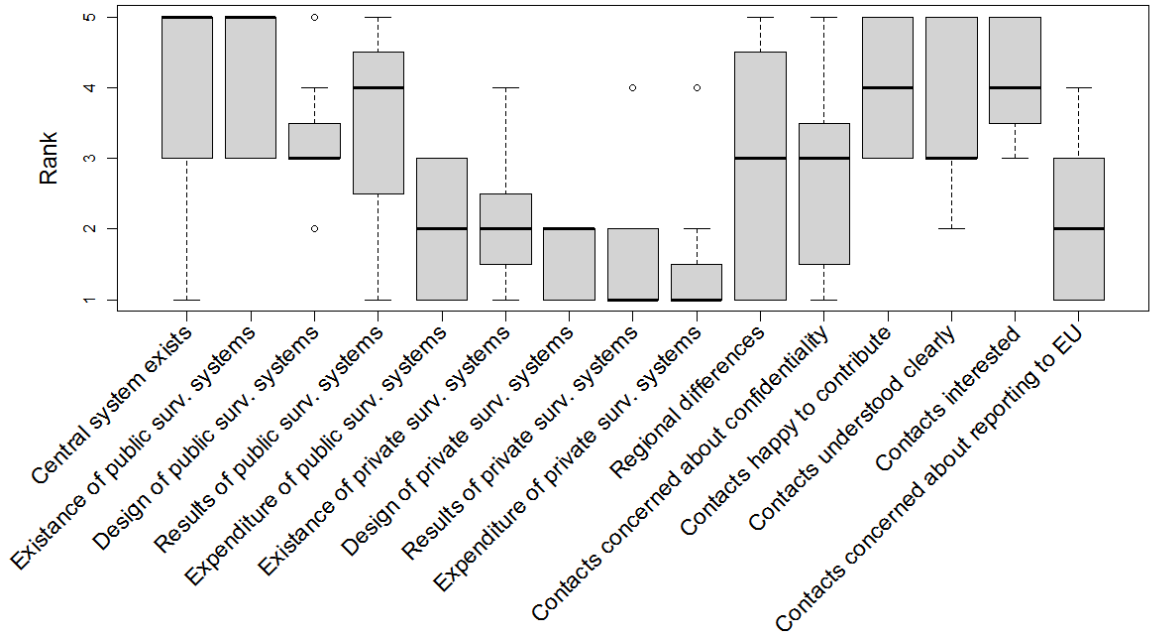

Figure 6. Median rank assigned by partner countries (*n* = 7) to statements of question 3 (see Section 7.2.3 for full wording) assessing the extent to which public and private surveillance systems were publicly documented, regional differences and attitude of people contacted to provide additional information. Responses were ranked on a scale from 1 (not applicable) to 5 (highly applicable). The category "Expenditure of public surveillance systems" included one missing answer.

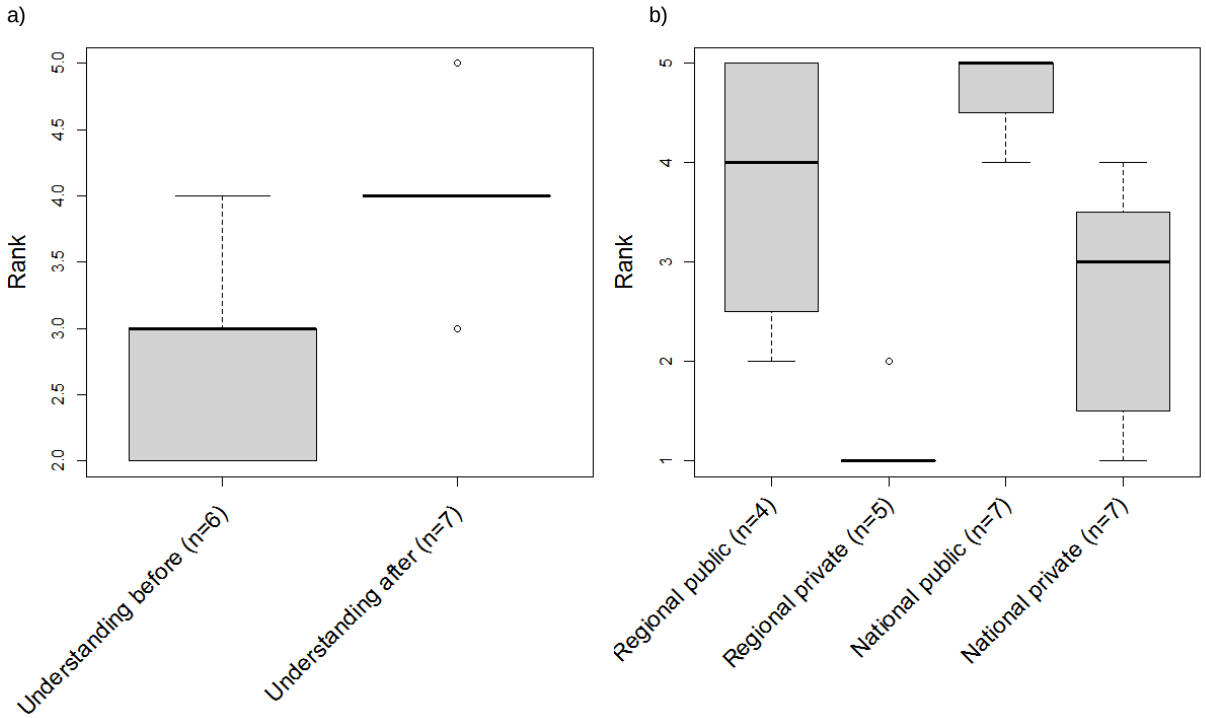

Figure 7. Median rank assigned by partner countries 1 to 7 estimating the confidence of the staff members involved in data collection that they clearly understood definitions and instructions before and after the consistency checks (Figure 7a relating to question 5) and the completeness of regional and national public and private components (Figure 7b relating to question 5). Responses were ranked on a scale from 1 (not applicable) to 5 (highly applicable). See Section 7.2.3 for the full wording of questions.

8 References

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