

Brussels, 13 April 2018

COST 021/18

DECISION

Subject: **Memorandum of Understanding for the implementation of the COST Action “Standardizing output-based surveillance to control non-regulated diseases of cattle in the EU” (SOUND-control) CA17110**

The COST Member Countries and/or the COST Cooperating State will find attached the Memorandum of Understanding for the COST Action Standardizing output-based surveillance to control non-regulated diseases of cattle in the EU approved by the Committee of Senior Officials through written procedure on 13 April 2018.



MEMORANDUM OF UNDERSTANDING

For the implementation of a COST Action designated as

COST Action CA17110 STANDARDIZING OUTPUT-BASED SURVEILLANCE TO CONTROL NON-REGULATED DISEASES OF CATTLE IN THE EU (SOUND-control)

The COST Member Countries and/or the COST Cooperating State, accepting the present Memorandum of Understanding (MoU) wish to undertake joint activities of mutual interest and declare their common intention to participate in the COST Action (the Action), referred to above and described in the Technical Annex of this MoU.

The Action will be carried out in accordance with the set of COST Implementation Rules approved by the Committee of Senior Officials (CSO), or any new document amending or replacing them:

- a. "Rules for Participation in and Implementation of COST Activities" (COST 132/14 REV2);
- b. "COST Action Proposal Submission, Evaluation, Selection and Approval" (COST 133/14 REV);
- c. "COST Action Management, Monitoring and Final Assessment" (COST 134/14 REV2);
- d. "COST International Cooperation and Specific Organisations Participation" (COST 135/14 REV).

The main aim and objective of the Action is to coordinate, stimulate and assist with initiatives to explore and implement a widely adaptable output-based framework applicable to substantiate the confidence of freedom and costs-effectiveness in current surveillance, control or eradication programmes for non-regulated cattle diseases in the EU.. This will be achieved through the specific objectives detailed in the Technical Annex.

The economic dimension of the activities carried out under the Action has been estimated, on the basis of information available during the planning of the Action, at EUR 88 million in 2017.

The MoU will enter into force once at least seven (7) COST Member Countries and/or COST Cooperating State have accepted it, and the corresponding Management Committee Members have been appointed, as described in the CSO Decision COST 134/14 REV2.

The COST Action will start from the date of the first Management Committee meeting and shall be implemented for a period of four (4) years, unless an extension is approved by the CSO following the procedure described in the CSO Decision COST 134/14 REV2.

OVERVIEW

Summary

Several countries have implemented programmes to control non-regulated cattle diseases in the European Union, impairing the comparison of the confidence of freedom for cattle originating from different countries. In order to facilitate safe trade, there is a need to support the development of transparent methods that enable comparison of outputs of surveillance, control or eradication programmes.

In this Action, Innovative methods for Standardizing OUtput-based surveillance to control Non-regulated Diseases in the EU (SOUND-control), work will be conducted in five workgroups to develop a generic and joint understanding about the requirements and characteristics needed for proof of freedom and subsequent costs-effectiveness, regardless of heterogeneities in the underlying data. SOUND-control will coordinate, stimulate and assist with initiatives to explore and implement a widely adaptable, output-based framework to substantiate confidence of freedom from infection and assess epidemiological and economic equivalence of control efforts.

The workgroups will describe current control programmes, provide requirements for an output-based framework, evaluate data availability and assess available and innovative methods for objective and standardised output-based comparison.

With the new Animal Health Law, it is anticipated that disease control will progressively change towards output-based approaches. SOUND-control will support the Animal Health Law by providing requirements and demands for a single general regulatory framework, adaptable to multiple diseases, which aims to enhance the safety of trade. Although the primary focus of this Action concerns non-regulated diseases, the outcomes of this work will be applicable to regulated diseases in the EU, which are currently underpinned by input-based standards.

<p>Areas of Expertise Relevant for the Action</p> <ul style="list-style-type: none"> ● Veterinary science: Veterinary medicine (miscellaneous) ● Veterinary science: Databases, data mining, data curation, computational modelling ● Animal and dairy science: Applied mathematics, statistics, non-computational modelling 	<p>Keywords</p> <ul style="list-style-type: none"> ● proof of freedom ● control programmes ● non-regulated diseases ● cattle ● output-based
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Specific Objectives

To achieve the main objective described in this MoU, the following specific objectives shall be accomplished:

Research Coordination

- Combine knowledge from numerous disciplines, including veterinarians, epidemiologists, economists, sociologists and stakeholders from governmental organisations and industry (All WG).
- Identify and reach agreement on the requirements (both scientific and practical) that should be met by a framework that aims at an objective comparison of the output of CPs for non-regulated cattle diseases in the EU (WG1).
- Identify the non-regulated cattle diseases for which control, eradication and/or surveillance are currently being conducted in the EU (WG1). The framework should be applicable to a large number of diseases, but will initially be designed for a few 'example diseases' with considerable variation between MS.
- Evaluate the availability and quality of the heterogeneous data that is needed as an input for an output-based framework. This will be evaluated at each level of aggregation and for each of the countries involved in the SOUND-control Action (WG2).
- Evaluate existing methods enabling output-based comparison of CPs and identify gaps (WG3).

- Encourage research initiatives that aim to take the next steps into development of innovative methodologies that tackle the gaps identified in WG3, including mathematic, epidemiologic, economic and social science methods, and facilitate the possibilities for short term scientific missions (STSMs) to combine expertise from different research areas (WG4).
- Disseminate the knowledge that is achieved during the SOUND-control Action and encourage incorporation of an output-based framework both on national and European level (all WG, but specifically addressed by WG5).

Capacity Building

- Fostering knowledge exchange on the characteristics of CPs conducted for relevant non-regulated cattle diseases in the EU in cattle (WG1).
- Generating a handbook or wiki page that can be accessed to acquire information on country specific CPs that are applied for non-regulated cattle diseases in the EU (WG1).
- Fostering experience on available methodologies that might be used (in an adapted form) for an objective comparison of output of different CPs and different initial situations with regard to the disease status (WG2, WG3).
- Developing a joint research agenda that offers the possibility to further develop an output-based framework to objectively compare outputs of CPs at different levels of aggregation that is applicable to a large range of diseases and meets the requirements of a large number of EU MS (WG4)
- Develop training materials that can be disseminated through seminars, workshops and conference presentations (WG5).
- Develop an open access platform to disseminate all knowledge and output that is obtained through SOUND-control to all interested stakeholders (WG5).
- Involving specific target groups such as Early Career Investigators (ECI), under-represented gender, researchers from Inclusiveness Target Countries (ITC).

TECHNICAL ANNEX

1. S&T EXCELLENCE

1.1. CHALLENGE

1.1.1. DESCRIPTION OF THE CHALLENGE (MAIN AIM)

SOUND-control aims to harmonise the outputs from different European Member States (MS) Control Programmes (CPs) for non-regulated cattle diseases, such as bovine viral diarrhoea (BVDV), paratuberculosis, *Mycoplasma bovis* and salmonellosis. Several European countries have already implemented national or regional surveillance, control, or eradication programmes for these infections. These programmes bring tangible benefits to participating farmers, and the industry because of increased health and welfare and reduced antibiotic use, and reduced direct losses (e.g. increasing production, and reducing morbidity and mortality rates) and indirect losses (e.g. trade constraints) associated with the specific disease. Therefore, development and participation in CPs are to be strongly supported. However, these programmes also create difficulties for intra-community trade, as trade has the potential to introduce infectious agents into regions where disease freedom has been achieved. The difficulties relate to differences in disease status between countries, and the lack of agreed methodologies to assess and compare confidence of freedom among cattle that are being moved between countries and regions. Although for non-regulated diseases no regulations exist at European level, an understanding of equivalence with respect to disease freedom or more correctly termed 'freedom from infection' is important when seeking to facilitate interstate animal movements, whilst also managing the risk of infection.

For notifiable cattle diseases, EU regulations are in place to help harmonise requirements for the free status of the animal, herd and/or country. The study design, sampling scheme and type of tests are generally prescribed by EU regulations, so-called 'input-based standards'. In contrast, 'output-based standards' do not prescribe what needs to be done, but rather what must be achieved. Enabling standardised comparison between outputs of CPs is important in light of intracommunity trade of cattle with potential substantial economic consequences.

SOUND-control will address the need for output-based standards for cattle diseases. The project will assemble researchers, stakeholders and policy makers from different countries to discuss the requirements and demands for an output-based framework. SOUND-control aims to coordinate initiatives to take the next steps in further development of an accessible and transparent output-based framework to allow the calculation of the probability of freedom from infection and subsequent cost-effectiveness to be calculated and compared between different CPs. SOUND-control will support the implementation of the Animal Health Law by providing requirements and demands for a single general framework, adaptable to multiple non-regulated cattle diseases in the EU, that aims to enhance the safety of intracommunity animal trade, whilst keeping flexibility.

In this proposal, the term 'Control Programmes' (CPs) is applied for programmes that lead to a free status from a certain disease at a specific level of aggregation i.e. animal, herd, region of country. In general, two components are distinguished when conducting a CP, i) a component that initiates action to eradicate the infection and ii) a component that monitors the progress and the subsequent free status. Both components are addressed as CP in this proposal.

1.1.2. RELEVANCE AND TIMELINESS

SOUND-control is highly relevant and timely because of the points addressed below:

- Many countries are implementing regional or national CPs for non-regulated cattle diseases in the EU for which, no generally accepted rules or guidelines are currently in place. Consequently, countries are generally developing their own CPs, often with considerable country-level variation in respect to both programme design and implementation. As a consequence, **uncertainty about the confidence of “freedom”** of traded animals is introduced. SOUND-control aims to develop a generic agreement on the requirements, demands and characteristics needed for proof of freedom from non-regulated cattle diseases in the EU, regardless of the heterogeneity of underlying data. The Action will create a European network of scientists (including epidemiologists, economists, sociologists, microbiologists, statisticians, modellers, veterinarians), decision makers and stakeholders. Within the Action, the practical implications of developing and applying a framework that enables evaluation of epidemiological and economical differences between CPs in different countries will be discussed.
- Surveillance, control or eradication of non-listed cattle diseases in the EU is important because it leads to a reduction in disease burden, improvement in the overall health and welfare of livestock, reduced medicine use and improves sustainability of livestock production. However, for countries that have achieved, or are realising, control and eradication of these diseases, **trade between different regions or countries currently poses a very tangible risk** of reintroduction of infections and diseases into susceptible populations. SOUND-control will support the development of methods to permit objective comparison of status between CPs for non-regulated cattle diseases in the EU.
- **Most animal health legislation for regulated cattle diseases in the EU is currently underpinned by input-based standards.** With the new Animal Health Law (AHL), this research proposal is timely as, within the AHL, there is a desire to implement output-based standards for regulated cattle diseases. This desire exists because of known weaknesses of input-based standards, but also because of the close alignment between output-based standards and flexible regulation. **SOUND-control will stimulate cooperation between countries towards the development and application of an output-based framework containing methodologies to objectively compare the output of control and surveillance systems on different levels of aggregation.** Although the focus of this proposal concerns non-regulated cattle diseases in the EU, **the outcomes of this work are applicable to regulated cattle diseases in the EU as well, and for situations where equivalence in control efforts between countries is under discussion.**
- Tailored solutions will evolve in the face of differing approaches to surveillance, control or eradication under different production systems, demographic situations and social acceptability in different countries (Lindberg et al., 2006). **Transfer of new knowledge**, will enable countries to learn from each other, and increase the probability of success with improved country-level efforts towards surveillance, control or eradication.
- There is a growing body of scientific literature supporting the development of output-based standards in animal health. As yet, however, there are **very few examples of the application of output-based standards in the field** (More et al., 2009; Cameron, 2012; Schuppers et al., 2012; Foddai et al., 2015). There is an urgent need to refine these methods to allow simple and practical field-based application. In SOUND-control, the available methods will be evaluated and required improvements and **initiatives will be identified to refine existing and developing innovative methods for field application of an output-based framework that is ultimately widely applicable to a large range of cattle diseases in the EU.**

1.2. OBJECTIVES

1.2.1. RESEARCH COORDINATION OBJECTIVES

The aim of SOUND-control is to coordinate, stimulate and assist with initiatives to explore and implement a widely adaptable output-based framework applicable to substantiate the confidence of freedom and costs-effectiveness in current surveillance, control or eradication programmes for non-regulated cattle diseases in the EU. This is defined by the following objectives:

- Combine knowledge from numerous disciplines, including veterinarians, epidemiologists, economists, sociologists and stakeholders from governmental organisations and industry (All WG).
- Identify and reach agreement on the requirements (both scientific and practical) that should be met by a framework that aims at an objective comparison of the output of CPs for non-regulated cattle diseases in the EU (WG1).
- Identify the non-regulated cattle diseases for which control, eradication and/or surveillance are currently being conducted in the EU (WG1). The framework should be applicable to a large number

of diseases, but will initially be designed for a few 'example diseases' with considerable variation between MS.

- Evaluate the availability and quality of the heterogeneous data that is needed as an input for an output-based framework. This will be evaluated at each level of aggregation and for each of the countries involved in the SOUND-control Action (WG2).
- Evaluate existing methods enabling output-based comparison of CPs and identify gaps (WG3).
- Encourage research initiatives that aim to take the next steps into development of innovative methodologies that tackle the gaps identified in WG3, including mathematic, epidemiologic, economic and social science methods, and facilitate the possibilities for short term scientific missions (STSMs) to combine expertise from different research areas (WG4).
- Disseminate the knowledge that is achieved during the SOUND-control Action and encourage incorporation of an output-based framework both on national and European level (all WG, but specifically addressed by WG5).

1.2.2. CAPACITY-BUILDING OBJECTIVES

The coordination, networking and dissemination activities of SOUND-control aims at:

- Fostering knowledge exchange on the characteristics of CPs conducted for relevant non-regulated cattle diseases in the EU in cattle (WG1).
- Generating a handbook or wiki page that can be accessed to acquire information on country specific CPs that are applied for non-regulated cattle diseases in the EU (WG1).
- Fostering experience on available methodologies that might be used (in an adapted form) for an objective comparison of output of different CPs and different initial situations with regard to the disease status (WG2, WG3).
- Developing a joint research agenda that offers the possibility to further develop an output-based framework to objectively compare outputs of CPs at different levels of aggregation that is applicable to a large range of diseases and meets the requirements of a large number of EU COST countries (WG4).
- Acting as a stakeholder platform (all WG)
- Develop training materials that can be disseminated through seminars, workshops and conference presentations (WG5).
- Develop an open access platform to disseminate all knowledge and output that is obtained through SOUND-control to all interested stakeholders (WG5).
- Involving specific target groups such as Early Career Investigators (ECI), under-represented gender, researchers from Inclusiveness Target Countries (ITC).

1.3. PROGRESS BEYOND THE STATE-OF-THE-ART AND INNOVATION POTENTIAL

1.3.1. DESCRIPTION OF THE STATE-OF-THE-ART

Most regulated diseases within the EU are underpinned by input-based standards. The proposers argue for the adoption of output-based standards, where emphasis is placed on the required outcome (proof of freedom) instead of the processes required to achieve this outcome. This is consistent with current thinking, where multiple passive and active surveillance components are combined to ascertain freedom of infection. Using this approach, scenario tree models and Bayesian methods have been developed (Martin et al., 2007; Heisey et al., 2014), and freedom calculations are based on outputs of a combination of surveillance components. Other recent advances include the development of latent class methods and inclusion of probabilistic definitions (Schuppers et al., 2012). There is an urgent need to optimize and refine these methods and to reach agreement on the definition of harmonised target prevalence levels to allow simple and practical field-based application to enable standardized comparison of outputs of CPs.

1.3.2. PROGRESS BEYOND THE STATE-OF-THE-ART

The ultimate goal of SOUND-control is the development of an agreed, harmonized output-based framework to estimate i) the probability of freedom from infection at different levels of aggregation and

ii) the related socioeconomic aspects of different CPs with heterogeneous inputs, including economic and sociological aspects of adopting such CPs. The SOUND-control Action will provide a platform to combine multidisciplinary expertise and create joint research agendas between EU COST countries to develop a broadly supported output-based framework that is widely applicable to a large range of cattle diseases in the EU.

The progress beyond the state of the art will be that SOUND-control will support development and uptake of new methodologies that are flexible in terms of i) incorporating imperfect/incomplete input parameters and ii) heterogeneous input data. The requirements in terms of diagnostics, management practices (contact structures and probability of introduction of diseases) and data management of an output-based framework will be discussed within the SOUND-control Action.

The Action will discuss and describe CPs that are currently in place in the EU COST countries. Transfer of this knowledge will enable countries to learn from each other, to optimise existing CPs and to increase the probability of success and cost-effectiveness of country-level efforts for new to develop CPs. Additionally, such a framework will stimulate development of additional control actions in order to limit the spread of infections through trade when the confidence of disease freedom is insufficient.

The SOUND-control Action will promote improvement, refinement and simplification of currently available and innovative methodologies (for example latent class, decision analyses including scenario tree models, cost-effectiveness analyses, and Bayesian methods optimized for the specific purpose of objectively comparing the outputs of CPs) into the development of an output-based framework.

1.3.3. INNOVATION IN TACKLING THE CHALLENGE

SOUND-control aims to stimulate the improvement and development of methodologies with which outputs of CPs of non-regulated cattle diseases in the EU can objectively be compared. For the regulated diseases there is legislation in place that lay down input-based requirements in order to evolve towards and maintain a free status. Because of differences in animal densities, housing systems and contact structures between countries, the general EU guidelines may not always be the most cost-effective option for surveillance, control or eradication purposes. The innovation potential of SOUND-control is that it will provide new technologies in which a range of methods (for example scenario tree modelling, latent class analysis and Bayesian inference such as Bayesian structural time series models) will be combined to provide a conceptual framework on which to objectively compare the confidence of freedom and cost-effectiveness of CPs for non-regulated cattle diseases in the EU. SOUND-control aims at the possibility that each of the EU COST countries is allowed to design and conduct their own tailor-made CPs as long as each programme provides a sufficient level of confidence, which is agreed upon by the participating stakeholders in SOUND-control of freedom of infection. Once developed, these methodologies can also be generalised to enable application to regulated cattle diseases in the EU, providing more flexibility and a simplification of the current regulations. SOUND-control aims at making these new technologies available for scientists, industry, governments and other stakeholders.

1.4. ADDED VALUE OF NETWORKING

1.4.1. IN RELATION TO THE CHALLENGE

For non-regulated cattle diseases in the EU, each country has its own specific control programme in place and it is not clear if herds that are defined as “free” within different programmes actually have an equivalent confidence of freedom. An international collaboration is needed to improve comparability of the confidences of freedom and cost-effectiveness resulting from different CPs. When considering the optimal CP, important socioeconomic aspects such as risk perception and factors hindering or motivating the adoption of CPs will be included as well.

In this Action, industry, stakeholders and scientists work together to address this issue and will combine expertise about CPs, experience in veterinary diagnostics, epidemiological analysis and socio-economic evaluations. Members of this COST Action work in close contact with the national veterinary officers, the national ministry of agriculture and the industry partners. During SOUND-control, each partner will inform and involve their relevant national contacts. The Cost Action will build on previous work performed

in recent European consortia such as EMIDA-ERA Early Detection Data, RISKSUR and others. The European Food Safety Authority (EFSA) has granted a thematic call (EFSA, 2016) that funds the technical components of a framework that enables objective and standardised comparison of CPs. The SOUND-control Action will ensure that the developed framework meets the requirements and standards of a large number of EU COST countries to maximise uptake. EFSA was already contacted for collaboration in SOUND-control and indicated that they are willing to act as an observer. In this way, SOUND-control will enhance collaboration on control of non-regulated cattle diseases between EU COST countries.

1.4.2. IN RELATION TO EXISTING EFFORTS AT EUROPEAN AND/OR INTERNATIONAL LEVEL

Currently, for a range of diseases there are on-going collaborations between countries (for example the work of European Federation for Animal Health and Sanitary Security (FESASS, www.fesass.eu) and the Committee of Professional Agricultural Organisations and General Confederation of Agricultural Cooperatives (Copa-Cogeca). Further, international research collaborations in animal health surveillance exist that are, or have been, financed through European funding (EMIDA, ANIHOWA ERA-net and, FP7-funded projects). Nevertheless, there have not to date been any international collaborations that provide a pathway by which output-based comparisons of CPs can be developed either from input-based programmes of *de novo* in the absence of pre-existing programmes. The SOUND-control Action will establish such a platform and stimulate international collaboration between countries to enhance transparency about the confidence of their 'free' status for multiple non-regulated cattle diseases in the EU. This consortium will act to promote networking, collaboration and knowledge transfer across multidisciplinary scientific teams, industry and stakeholders on the implementation of CPs of non-regulated cattle diseases in the EU. This Action will provide a setting in which a common strategy will be developed in order to harmonize outputs of animal health CPs'. In addition to this collaboration, a complementary four-year research initiative to cover the technical work was granted for funding in the 2016-1 thematic grant call of EFSA (EFSA, 2016) and started in 2017. The aim of the EFSA call is to develop an easily accessible and implementable output-based methodology to allow standardised comparison of the probability that an animal, herd, region or country is free from infection of non-regulated diseases. The two projects will be fully complementary i.e. a network for input and dissemination in combination with a project in which a part of the technical work, i.e. the development of an output-based framework for non-regulated diseases, is conducted. The SOUND-control Action will facilitate interaction with a large number of EU COST countries, thereby magnifying input into, and dissemination from, the EFSA-supported research project. In addition, each of the SOUND-control Action participants will contribute to the further development, implementation and expansion of the framework, to meet the needs of a large number of stakeholders. This will enhance support, applicability and possibility of international implementation of an output-based framework to compare freedom from disease across a range of non-regulated cattle diseases. Thus, there will also be added value in the obvious possibilities of benchmarking practicalities and cost-effectiveness of the CP's in different countries.

2. IMPACT

2.1. EXPECTED IMPACT

2.1.1. SHORT-TERM AND LONG-TERM SCIENTIFIC, TECHNOLOGICAL, AND/OR SOCIOECONOMIC IMPACTS

Short-term impact

SOUND-control will form a multidisciplinary team of researchers, industry and stakeholders to evaluate CPs conducted for non-regulated cattle diseases in the EU that are in place in the COST countries given the countries' specific demographic context. This information will be combined in either a handbook or wiki page that is one of the outputs of SOUND-control (D1.3). In the Action, knowledge will be shared (all WG), available data will be evaluated (WG2), literature will be reviewed (WG3) and a joint research agenda will be created. This will support the development and implementation of an innovative and easy to use output-based framework to compare the confidence of freedom and the costs i.e. the cost-

effectiveness between different programmes, and set priorities for further research. The knowledge that is available through each of the partners collaborating in the Action will be shared through several workshops, Skype meetings, WG meetings, webinars, etc. in order to enhance mutual learning. The expected short-term impact will be a more in-depth view of the steps that have to be taken to improve safety of trade with regard to transmission of non-regulated cattle diseases in the EU. Despite the wide range of different surveillance processes (or CP) encountered in the different countries, a common understanding and a flexible tool shall enable to compare each others achievements in terms confidence of freedom and cost-effectiveness taking into account uncertainty and variability of certain parameters. The newly developed knowledge will be further consolidated and disseminated by STSMs and webinars.

Long-term impact

Through the networking and dissemination activities within all WGs but specifically in WG5, SOUND-control will establish long-term collaborations and lay the scientific basis for policies aimed at improving the safety of intra-community trade in cattle. SOUND-control aims to evaluate possibilities for funding for further development of an easy to use and ready to implement output-based framework. The developed framework may be implemented at EU level to improve the safety of trade and could be expanded for comparison of regulated cattle diseases in the EU that are currently controlled based on inputs (i.e. type of samples and tests, sample size and frequency of testing). The long term impact of the developed methodology is guaranteed as SOUND-control will ensure that the developed method will incorporate the requirements and characteristics of the partners within SOUND-control. This will result in a methodology that is supported by researchers, industry partners and policy makers in a large number of EU COST countries who are involved in the SOUND-control Action.

2.2. MEASURES TO MAXIMISE IMPACT

2.2.1. PLAN FOR INVOLVING THE MOST RELEVANT STAKEHOLDERS

To maximize the probability that SOUND-control results in intra-EU collaborations that tackle the trade issues for non-regulated diseases in the EU, by development and implementation of an output-based application, the outreach activities will be targeted towards all relevant stakeholders. Representatives from several key stakeholders are already proposers of SOUND-control and other relevant stakeholders may involve farmer's both on national and EU level (such as Copa-Cogeca, Federation of Veterinarians in Europe (FVE), World Trade Organisation (WTO), etc.), veterinarian organisations, trader organisations, industry, the national Chief Veterinary Officers (CVOs) and international organisations such as EFSA, the World Organisation for Animal Health (OIE) and Food and Agriculture Organisation of the United Nations (FAO). As part of WG1, a representative of each of the COST countries involved in the Action will map the relevant stakeholders for the non-regulated cattle diseases that will be evaluated. These key stakeholders will be informed about the project and invited to participate in workshops and webinars. National key stakeholders and CVOs will be actively informed about the progress of SOUND-control through periodical newsletters. Through the additional dissemination activities outlined in WG5, a wider circle of stakeholders will be informed about the SOUND-control activities.

2.2.2. DISSEMINATION AND/OR EXPLOITATION PLAN

Dissemination of the knowledge generated by SOUND-control will occur at three different levels.

At the first level, key stakeholders will be identified by the core group (CG) and actively approached to determine whether they are interested in participating as partners in the Action and/or participate in the workshops that are organized as part of SOUND-control. The second level involves stakeholders relevant to SOUND-control that work in the area of non-regulated and regulated cattle diseases in the EU, monitoring and surveillance, output-based modelling and trade. Both the first and second level stakeholders will be actively informed on the progress of SOUND-control via periodic newsletters. The third level involves a wide circle of stakeholders and people that might be interested in the Action, including possible end-users such as programme managers, regulators and representatives from other

animal sectors. Stakeholders on all three levels will be informed on the Actions' progress through the open access SOUND-control website, webinars, presentations and workshops at relevant conferences and through inviting them to participate in the final conference in which all SOUND-control achievements are presented. This conference will be targeted at involving the stakeholders from all three levels. Additionally, representatives from farmers organisations, food producing and animal health industry on national and EU level will actively be contacted and invited to join.

Among policy-makers, there is a clear recognition that outcome-based approaches are a desired endpoint, and it can be expected that they are keen to be involved. Exploitation of the results will occur by working closely with these policy-makers (at EU level and nationally), both to ensure and to demonstrate the practicality of the work for policy decision-making. Many members of the network work closely with their national CVOs and policymakers and will request their involvement in this Action.

2.3. POTENTIAL FOR INNOVATION VERSUS RISK LEVEL

2.3.1. POTENTIAL FOR SCIENTIFIC, TECHNOLOGICAL AND/OR SOCIOECONOMIC INNOVATION BREAKTHROUGHS

The prospects for success of the SOUND-control Action are very high because the Action aims at providing a basis for development of an easy to use output-based framework that enables standardised and objective comparison of the confidence of freedom and subsequent cost-effectiveness evaluations for non-regulated cattle diseases in the EU. Such comparison will provide insight in both the confidence of freedom and the costs and benefits involved and may stimulate adapting existing CPs and the development of new cost-effective CPs controlling and eradicating endemic diseases throughout the EU. Previous work has shown that considerable cost-reductions can be achieved (Stott et al., 2012; Pinior et al., 2017).

Potential for scientific breakthrough

Within the new Animal Health Law, there is a desire to adopt output-based standards for regulated cattle diseases in the EU. Currently, there are only a few examples of output-based standards in the field and although considerable progress is described in the scientific literature, an easy to use method that allows standard and objective comparison of CPs is not yet available. SOUND-control will evaluate all existing methods, identify gaps and evaluate the potential to combine existing methodology with new techniques. The results of this Action will serve as scientific input for the important policy discussion how to develop a framework that is easy to use and can be applied to objectively compare outputs of CPs of multiple livestock diseases.

Potential for technological breakthrough

There is a growing body of scientific literature to support development of output-based standards in animal health and part of the fundamental issues have already been resolved. However, the desired method, which involves a framework that is practical implementable and suitable for widespread use in the field, is not yet available. In SOUND-control the gaps in the current methods will be defined and it will evaluate how existing methods should be combined with new techniques to meet all demands and requirements set by the partners of SOUND-control.

Potential for socioeconomic breakthrough

SOUND-control will ensure that a developed framework will incorporate the requirements and demands of stakeholders in a large number of countries. The returns of the Action are substantial when the Action is successful, specifically in generating a means to quantify freedom for a range of animal health issues resulting in the facilitation of output-based CPs. Combining the knowledge of the epidemiologic and economic characteristics of all CPs throughout the EU COST countries, supports the movement towards the next generation of CPs which are established on output instead of input-based standards, provide a accurate confidence of freedom while being cost-effective (Welby et al., 2015; Veldhuis et al., 2017).

Additionally, the framework will create awareness about the disease status and thus stimulates the development of new CPs on regional and national level, which is beneficial for all EU countries.

3. IMPLEMENTATION

3.1. DESCRIPTION OF THE WORK PLAN

3.1.1. DESCRIPTION OF WORKING GROUPS

SOUND-control will result in publications, a handbook or wiki-page, reports and a website (i.e. codified knowledge). The tacit knowledge resulting from SOUND-control involves enhanced knowledge on output-based frameworks for all stakeholders involved and informed through this Action. In addition, a data availability matrix which will be filled by each of the participating EU COST countries will be developed (technology). All these types of knowledge that will be developed during SOUND-control will be used to increase the active participation of stakeholders and to stimulate uptake and ongoing improvement of an eventual developed output-based framework beyond the lifetime of this Action. The work that is foreseen within the SOUND-control Action shall be conducted within five different working groups (WG). Several methods will be used to achieve good communication within WGs and excellent integration between WGs. Firstly, there will be frequent moments of contact as described in paragraph 3.2 (monthly telco's within each WG, bimonthly contact moment between the members of the CG i.e. between WGs). Secondly, annual face-to-face meetings will be held to share the progress and results of all WGs between the participants and to discuss the findings.

WG1. Characteristics of existing CPs and requirements for an output-based framework

Objectives: WG1 will evaluate i) for which non-regulated cattle diseases in the EU CPs are conducted in COST countries, ii) the relevant stakeholders involved in the application of these CPs, iii) the characteristics of these programmes, and iv) identification of the essential requirements needed as inputs for an output-based framework. The entire chain of control points in disease CPs will be studied such as the country specific epizootiological situation in herds, sample matrices to be used, diagnostics, evaluation of diagnostic results, application of epidemiological measures on the farm, sociological aspects and costs of different CPs and experiences from users that already have been successful in the eradication of endemic diseases.

Tasks and Activities

T1.1. Create an overview of all non-regulated cattle diseases in the EU in cattle for which CPs are in place in the COST countries including the relevant stakeholders that are involved in each of the COST countries.

T1.2 Collect information on the epidemiological, economic, social and political characteristics of different CPs applied in the control of non-regulated cattle diseases in the EU.

T1.3 Development of a handbook or wiki page describing the characteristics of CPs that are applied in the control of non-regulated cattle diseases in the EU. The strengths and weaknesses of the different programmes in terms of ability to prevent new infections, early detection, acceptance by the stakeholders and the different contexts in which these CPs are applied will be evaluated.

T1.4 Define the required output that has to be provided by an eventual developed framework and reach a joint understanding on the minimum level of confidence that CPs have to provide.

Milestones

M1.1 Workshop involving the WG leaders together with the governmental representatives from all countries involved in the Action. The aim of this workshop is to create an overview of all non-regulated cattle diseases in the EU for which CPs are in place that will be included in the Action.

M1.2 Mid-term review involving the CG and management committee (MC) evaluating the progress.

M1.3 First draft of an overview of the non-regulated cattle diseases in the EU in cattle for which CPs are in place with their characteristics and background information.

M1.4 Workshop involving both multidisciplinary scientists and other stakeholders in which the defined key parameters that are required in an output-based framework are discussed, definitions of these parameters will be harmonized and agreement will be reached about the minimum required confidence of freedom provided by CPs at animal, herd, regional and national level.

Deliverables

D1.1 Overview of non-regulated cattle diseases in the EU for which CPs are in place within COST countries.

D1.2 Contact list of all relevant stakeholders that are involved in the application (either practical or regulatory) of CPs of non-regulated cattle diseases in each of the COST countries.

D1.3 Handbook or wiki page describing the different CPs in place relative to the farming systems, including parameterisation, strengths and weaknesses in terms of ability to prevent new infections, ability for early detection of new cases, costs and acceptance by the stakeholders.

WG2. Data requirements and availability

Objectives: To evaluate the availability of data that is required as input for an output-based framework. In WG2 the availability of data, the quality of the data and whether data are available on national or regional level will be evaluated for each of the countries involved in the Action.

Tasks and Activities

T2.1 Workshop to discuss the data that is required to serve as input for an eventual output-based framework, including coverage, the quantity and quality of available data. This will result in a data availability matrix that can be filled in by each of the countries involved in the Action.

T2.2 Determination of the characteristics of the available data, the required amount of detail that is required and definitions of poor/fair/good quality data.

T2.3 Evaluation of the data that is available in each of the countries that participate in the Action.

Milestones

M2.1 Workshop to discuss the essential parameters when evaluating confidence of freedom of infection, definitions of the characteristics and the required detail for each input parameter.

M2.2 Finalizing an assessment for applications to conduct STSMs aiming at gaining information on data systems that are used in EU countries for standardisation and registration.

M2.3 WG meeting in which the first draft of the data availability matrix is discussed and completed combined with a mid-term review involving the core group and MC presenting the progress so far.

M2.4 WG meeting discussing the final version of the data availability matrix and presenting the knowledge and experience that was obtained during the STSMs.

Deliverables

D2.1 A data availability matrix for each of the countries that participate in the SOUND-control Action, the input parameters that are required are described and information on the availability of the data is provided, along with an assessment of its quality and regional coverage.

D2.2 A report, describing the methods, results and recommendations resulting from the STSM.

WG3. Evaluate existing methods with potential for output-based comparison of CPs

Objectives: Identification of the gaps in existing methodologies and evaluation of the possibility to adapt existing statistical and mathematical methodologies in veterinary science and epidemiology for standardised comparison of disease CPs. Characteristics that will be evaluated include the flexibility to incorporate heterogeneous input data, robustness of the method, reliability and confidence of the output, ease of use and applicability to all interested parties. Additionally, also cost-effectiveness, social acceptability and generalizability to regulated diseases will be evaluated. The results of WG1 (requirements for an output-based framework) and WG2 (data availability) provide important input for WG3.

Tasks and Activities

T3.1 Review and evaluation of existing methods that might be used to quantify outputs of CPs.

T3.2 Ranking of methodologies based on adaptability to account for heterogeneous input data.

T3.3 Gaining hands-on experience with methodologies that are used to evaluate CPs in the countries that are involved in the SOUND-control Action during STSMs.

T3.4 Promote the best approaches and recommend further steps to be taken in order to develop a conceptual framework that fulfils all needs (including economic, sociologic and political aspects) and that can be applied for output-based comparison of non-regulated as well as regulated diseases.

Milestones

M3.1 Workshop with scientists of multiple countries and multidisciplinary backgrounds, including epidemiology, mathematics, statistics, economics, sociologic and veterinary science that evaluate existing methodologies that might be applicable for comparison of outputs derived from heterogeneous inputs.

M3.2 Finalizing an assessment for applications to conduct STSMs aiming at evaluating existing output-based methodologies on data of specific disease CPs.

M3.3 WG meeting in which all evaluated methodologies are ranked on relevance, their flexibility in terms of adaptability to provide an objective and harmonised output-based comparison of CPs (including economic, sociologic and political aspects) and their potential for enhancement towards output-based comparison of regulated diseases. The remaining knowledge gaps will be detected and described.

M3.4 Mid-term review involving the core group and MC presenting the progress so far.

M3.5 Webinars disseminating the knowledge and experience that was obtained during the STSMs.

M3.6 Workshop discussing the WG meeting results, resulting in recommendations on the remaining knowledge gaps and possibilities for combining current methodologies with innovative methods in order to create a method that fulfils all demands set by WG1.

Deliverables

D3.1 Report on comparison of different methodologies that can be applied to evaluate the quality of CPs, including an overview of the gaps for application of standardised comparison of outputs of both non-regulated and regulated diseases in the EU.

D3.2 Report with the results of the STSMs and subsequent material for conducting a webinar.

D3.3 Recommendations on the usefulness of current methodologies for providing standardised outputs of disease CPs, including a joint overview with recommendations on the knowledge gaps in the current methods that have to be fulfilled with a newly developed framework.

WG4. Stimulate initiatives aiming at development of methodologies that address knowledge gaps

Objectives: Development of a joint research agenda about possibilities to combine heterogeneous inputs into an output-based framework that is applicable to a large number of non-regulated cattle diseases. SOUND-control will encourage research initiatives that aim to develop a novel and easy to use methodology for objective comparison of outputs i.e. confidence of freedom, cost-effectiveness, social and political acceptability of CPs at different levels of aggregation. The results of WG1 (requirements for an output-based framework), WG2 (data availability) and WG3 (evaluation of existing methods) provide important input for WG4. In addition, the applicability of the framework for regulated diseases will be considered.

Tasks and Activities

T4.1 Organise a brainstorming with scientists from multiple disciplines in order to discuss the requirements for the next steps to be taken in development of new methodologies and plans to create these.

T4.2 Plan and promote case studies and STSMs to combine knowledge leading to new initiatives for developing a framework for output-based comparison.

T4.3 Conducting at least three STSMs by early career investigators (ECIs) to combine knowledge on existing methods and stimulating the development of new ideas.

T4.4 Development of a joint research agenda.

Milestones

M4.1 Brainstorming session involving scientists from multiple disciplines on the possibilities to develop a framework that fulfils all requirements and gaps that were defined in WG1 and WG3.

M4.2 Assessment of applications for STSMs leading to approval of at least three STSMs that aims to combine multidisciplinary experience in existing methodologies between countries.

M4.3 Mid-term review involving the core group and MC presenting the progress so far.

M4.4 Workshop presenting the results of the STSMs, identification of the ideas which have the widest applicability and identification of next steps, including possibilities to apply for funding.

M4.5 WG meeting in which a joint research agenda is developed between partners describing the next steps in the development of a novel and widely adopted framework that enables objective comparison of outputs of CPs at different levels of aggregation while being user friendly, robust, reliable and enabling heterogeneous input data.

Deliverables

D4.1 Overview of the results of the brainstorm session on the needs and possibilities for developing methods for an output-based comparison of the confidence of freedom from infection that is applicable to numerous cattle diseases.

D4.2 Report with the methods, results and recommendations of the different STSMs.

D4.3 A joint research agenda for development of a framework that enables objective comparison of outputs of CPs for non-regulated cattle diseases in the EU.

WG5. Dissemination and adoption

Objectives: Dissemination of knowledge obtained during the SOUND-control Action, including creating awareness of the importance of the need for development of an easily accessible framework that enables a harmonized and objective comparison of confidence of freedom as an output of different CPs. With the dissemination activities, SOUND-control aims to reach COST Member Countries, Near-Neighbour Countries and COST International Partner Countries to create awareness of the issue and create awareness of the importance to collaborate.

Tasks and Activities

T5.1 Create an open access SOUND-control website containing all information of the project and instructions on possibilities to collaborate in the Action.

T5.2 Creation of an international multidisciplinary group of scientists, industry members, policy makers and other relevant stakeholders on animal trade in relation to non-regulated cattle diseases in the EU to join the Action.

T5.3 Defining level one, two and three stakeholders (see paragraph 2.2) and actively approach stakeholders that are included in level one to requesting participation in the Action and/or in the workshops that are organized as part of SOUND-control.

T5.4 Organising webinars providing updates and information of the SOUND-control project to everyone who is interested.

T5.5 Developing annual newsletters informing interested parties on the progress of the project.

T5.6 Presentations and workshops of the progress and achievements of SOUND-control on relevant conferences to underline the importance of this work.

T5.7 Organisation of a final conference in which all SOUND-controls achievements are presented.

Milestones

M5.1 WG meeting to discuss and finalize the dissemination plan.

M5.2 Launch of the SOUND-control website.

M5.3 Mid-term review involving the core group and MC presenting the progress so far.

M5.4 Webinar presenting the SOUND-control Action and progress.

M5.5 Pre- or post-conference workshops on output-based comparison of CPs.

Deliverables

D5.1 Dissemination plan, for knowledge obtained during the SOUND-control Action to all relevant stakeholders.

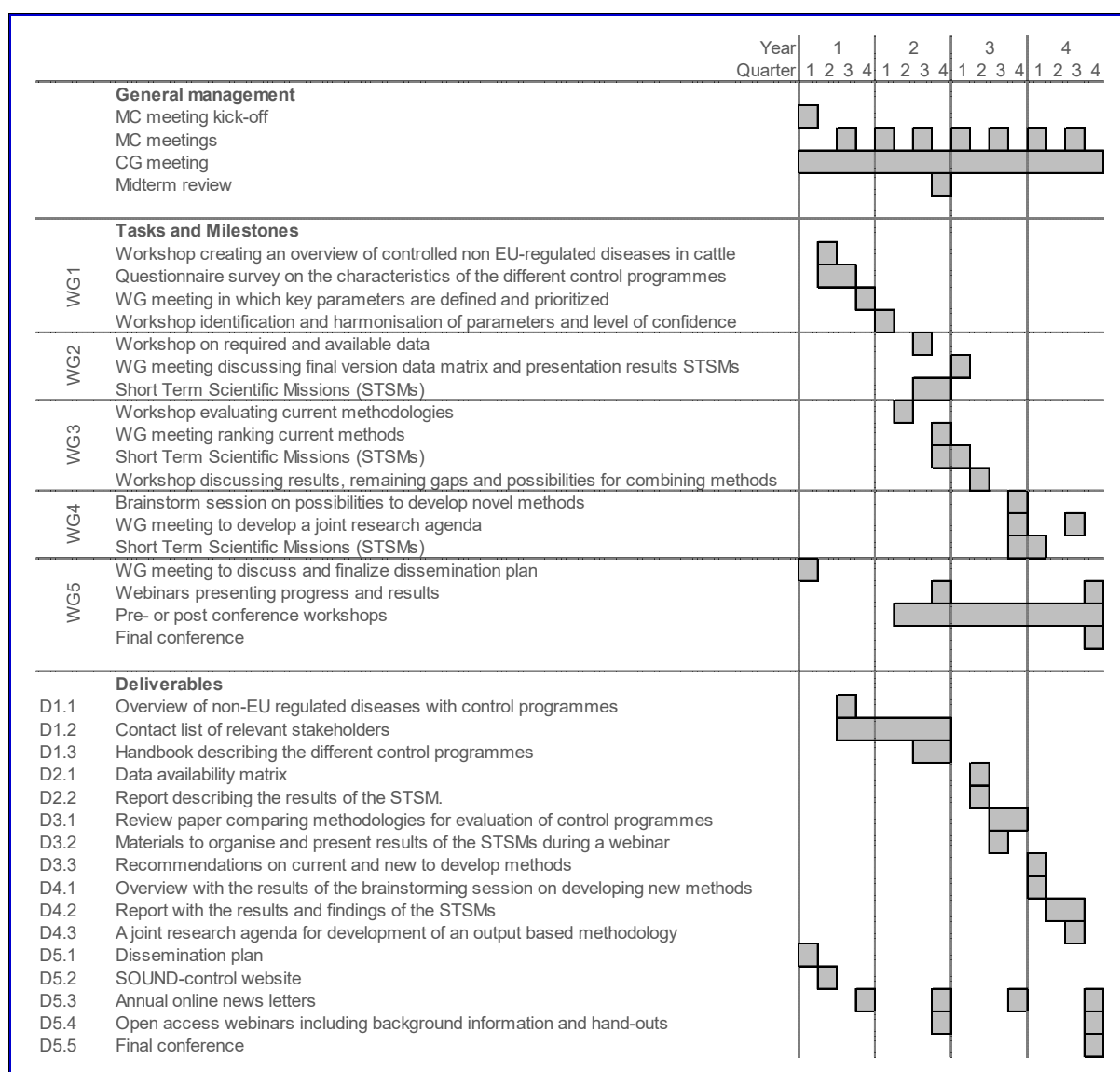
D5.2 The SOUND-control website is online and can be accessed. The members of the Action have internal page to share documents on a confidential basis.

D5.3 Annual online news letters, describing the milestones and the progress of the action..

D5.4 Open access webinars are organised and background information and hand-outs are developed. The webinars will be organised at midterm and at the end of the Action.

D5.5 Final conference is organised in which all knowledge obtained during the Action is disseminated to scientists, policymakers and other interested stakeholders. Additionally, the future prospects of the knowledge that was developed during the SOUND control Action will be discussed.

3.1.2. GANTT DIAGRAM



3.1.4. RISK AND CONTINGENCY PLANS

The MC will be responsible for the progress of the Action and will monitor in collaboration of the CG. Bi-annual reports are delivered enabling prompt identification of problems. If these are detected, the WG will immediately apply contingency measures such as direct intervention by members of the WG, holding additional meetings to identify and implement solutions.

Risk	Likelihood	Severity	Contingency measure
Complexity of the network is too high.	medium	low	Enhanced support from MC
Insufficient communication	low	medium	Implementing fixed moments for communication
Delay in WG deliveries	medium	medium	Set strictly monitored interim dead-lines. Ensure that different WGs can be conducted in parallel.
Cancellation of events	low	medium	Plan additional events.
Poor management of WG	low	medium	Selection of experienced WG leaders wit. If poor management occurs, MC will provide enhanced support and if not improved, will replace the WG leader.
Development of output-based system is impossible because of insufficient quality of data	low	medium	Countries with data quality issues will get a clear idea what improvements are necessary.
Partners do not deliver	medium	medium	Shared responsibilities for each of the tasks. Use of within-project communication tools to allow progress by each country to be objectively and transparently tracked.
Lack of involvement of European organisations	low	high	The MC will ensure involvement of the national policymakers. The chair and vice chair will have the responsibility to inform and involve EU level organisations.
Difficult to persuade stakeholders and policy makers to participate in the Action	low	high	The importance of this Action is already acknowledged by policy makers and stakeholders and part of the stakeholders already participate in this Actions as proposers. The proposers of this Action will use their personal network and will each convince their national stakeholders to participate.
Lack of interaction between WGs	low	high	This is unlikely to occur given the frequent contact between the members of the CG, the frequent Skype meetings that are planned and the annual events in which the progress of all WGs are presented and discussed
Lack of involvement COST ITCs, which will reduce the impact of the overall project	low	medium	Five ITC countries are already involved that will ensure involvement of their own national policymakers. In the dissemination plan evaluation of contacts in ITC countries and actions to invite them to participate will be incorporated.
No funding is found to finance the technical aspects	low	high	The importance of this work is already acknowledged by both national and EU organisations, this has resulted in a thematic call for development of a framework that enables objective and standardised comparison of CPs.

3.2. MANAGEMENT STRUCTURES AND PROCEDURES

The SOUND-control Action will strictly follow the COST rules described in document 132 to 135 (Action implementation rules). The MC that consists of a group of researchers, will be nominated by the COST National Coordinators, will be the main decision-making body and is composed of up to two representatives of each COST country. The MC will be overseen by a chair and vice-chair and will coordinate the Action. The MC will meet at least twice a year to discuss the Action structure, coordination and implementation of the Action activities, allocation, use of the COST budget and whether additional participants should be invited. Each COST Country and Cooperating State participating in the Action has one vote in the MC and decisions are taken based on the majority of votes of the MC members present. After selection of MC, the Action starts with a general meeting in which the MC chair, MC vice chair and grant holder are elected. Additionally, the MC will assign a leader and co-leader to each of the five workgroups (WG). The WG leaders should preferably originate from different COST countries and will be elected based on background, leadership and COST scheme experience. The co-leaders should preferably consist of ECIs. The MC chair and MC vice chair will form a core group (CG) together with the WG and will meet (either face-to-face or by Skype/video conferencing) at least every two months. The CG will support the Actions goals by designing the activities and monitoring the Actions' progress.

The WG leader and co-leader will jointly coordinate the activities within the WG, will chair the WG Meetings and will prepare annual progress reports. (Bi-)monthly Skype meetings will be held to monitor the progress of the activities within the WG. The progress reports will form the basis of the scientific and financial reports written by the MC and may constitute bases for the external monitoring by the independent Action rapporteur. WG and CG Meetings will be held alongside the MC Meetings to minimise travel costs.

Balance with respect to gender, race, nationality will be respected and participation of young researchers will be taken into account when nominating formal positions within the Action. All publications and dissemination tools resulting from the SOUND-control Action will comply with the COST checklist for publications. Each publication and dissemination activity has to be approved by the MC.

3.3. NETWORK AS A WHOLE

The inclusion of multidisciplinary scientific teams, industry and stakeholders will maximise the uptake of the results of SOUND-control and sustainability of the network, during and beyond the duration of this Action. The proposers combine a wide range of expertise on CPs of non-regulated cattle diseases, veterinary diagnostics, epidemiological and socioeconomic analyses. The network of proposers was designed to include all components needed to achieve the goals of the Action. The SOUND-control Action aims to include policymakers and stakeholders from many European countries, which will give a common platform to discuss initiatives to explore and implement a widely adaptable output-based framework. European organisations such as EFSA and FESASS are already contacted to be involved in this Action and are prepared to be actively involved in SOUND-control (FESASS) or to act as an objective observer (EFSA). When this Action is granted, national policymakers and stakeholders of other European agencies such as Copa-Cogeca will be contacted with the request to be involved.

Network enlargement: SOUND-control will aim to enlarge the network during the course of the Action. Stakeholders and policymakers from EU COST countries not yet involved in SOUND-control will be contacted to join, to provide a solid basis for acceptance of the developed output-based framework, enhancing trade safety.

Although most intra-community trade of animals occurs among EU COST countries, stakeholders and policy makers from NNC and IPC will be actively contacted through the existing network of the partners involved in SOUND-control. They will be requested to join the Action and to provide feedback. During the Action, participants may nominate potential experts that can be actively approached to enquire whether they are interested to participate as member or *ad hoc* participant. Through dissemination, other stakeholders, governmental authorities, policy makers and scientists from multiple fields will be actively informed about the progress of the Action and will be invited to workshops and conferences. Within a period of twelve months after approval of the Action, any COST country or cooperating state can join the Action. After this period the MC agreement and a signed MoU, to the CNC nomination is needed.