Protocol for the evaluation of EU-wide surveillance networks on communicable diseases

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LIST OF ABBREVIATIONS

CAV = Community added value CDC = Centers for Disease Control and Prevention CESE = Council of European State Epidemiologists DG SANCO = Directorate General – Health and Consumer Protection DSN = Dedicated Surveillance Network ECDC = European Centre for Disease Prevention and Control EPIET = European Programme on Intervention Epidemiology Training ESCON = Epidemiological surveillance component of the Community network EU = European Union EWRS = Early Warning and Response System FETP = Field Epidemiology Training Programme MS = Member State PHP = Public Health Programme WHO = World Health Organisation

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1 Executive summary

European surveillance on communicable diseases has developed rapidly after Decision 2119/98/EC established a Community network for epidemiological EU-wide surveillance and early warning and response system. The surveillance at EU level is targeted to cover over 40 diseases/health issues specified by the Commission Decisions 2000/96/EC and its recent amendments 2003/534/EC and 2003/542/EC.

Some surveillance networks have been created as early as in 80's and have been funded as concerted actions by DG-Research and as ad hoc projects by DG-SANCO. As a result, the networks differ in size, details, structure of organisation, and development phase. The Commission Decision 2003/542/EC identified for the first time for which diseases/special health issues there are so-called dedicated surveillance networks (DSNs) in place in which all Member States should participate and specify a contact point. These DSNs cover a number of the diseases to be under EU-wide surveillance and, as such, have an important role for the surveillance of communicable diseases at the EU level.

A recommendation to undertake an external evaluation of each of the surveillance networks and at three- to five-yearly interval has been made by Ruutu et al (2001). The protocol developed by the SURVEVAL project, presented in this document, provides a standardised tool for the independent, external evaluation of surveillance networks (including the DSNs) by experts in international surveillance on communicable diseases.

The overall aim of an external evaluation using the protocol in this document is to assess whether the specific surveillance methodology by the surveillance networks appropriately addresses the diseases/health issues in the European population, and whether the technical performance of surveillance is adequate to achieve appropriate level of Community added value (CAV). The evaluation addresses the following questions:

- 1. What is the potential added value from the international surveillance for the disease/health issue
- 2. How effectively has the surveillance network met its potential to provide added public health value?
- 3. What have been the major obstacles preventing the surveillance network from achieving its potential added value?
- 4. Has the effectiveness of the surveillance network in meeting its potential added value improved since a previous evaluation?
- 5. What are the recommendations to improve the current situation?

The data is to be collected both from the pool of national experts on the diseases/health issues under surveillance, e.g. the coordinating hub, the national contact points of the surveillance network, and the key national stake holders (State Epidemiologists). The evaluation is based on specific questions reflecting both the CAV and technical performance of the surveillance network within five subject areas:

- 1. Usefulness of the operation at national and international level
- 2. Development of the national surveillance systems
- 3. Quality of the outputs
- 4. Technical performance (e.g. timeliness, sensitivity and specificity)
- 5. Structure and management

Based on the measured specific performance parameters, an evaluation report will conclude with a synthesis of achieved CAV and major and minor findings regarding strengths and weaknesses of the operation of the surveillance network. Major weaknesses require urgent action by the surveillance network.

2 Introduction

The structure of the existing Community network on communicable diseases is built upon EU-wide epidemiological surveillance and early warning and response system, which have been laid down by the Decision 2119/98/EC and the Decision 2000/57/EC, and recognised through Commission Decisions on priority list of diseases (2000/96/EC, 2003/534/EC) with the amendment of specifying the operating procedures to be addressed by the dedicated surveillance networks (2003/542/EC). Decision 2003/542/EC identified for the first time that for 12 diseases/special health issues there are so-called dedicated surveillance networks (DSNs) in place as identified by an asterisk. In addition, to these DSN there are (and have been) other EU-wide surveillance networks in place that have not formally been recognised as a DSN (see for more detail the Technical guidance document as regards the operation of dedicated surveillance networks and on-going surveillance projects regarding communicable diseases in the context of the Community Network, WD 110/v2final). For reasons of simplicity, in the remainder of the text all EU-wide surveillance networks are referred to as DSN. The priority list covers over 40 diseases or special health issues. For many of these, the EU-wide networks of national experts have been created since early 80's. These surveillance networks have a central role for the surveillance of communicable diseases at the EU level. DSNs aim at providing information needed for detection of international health threats and prevention and control on communicable diseases both at the EU and the Member State (MS) level and, thus, provide European added value for public health.

As a number of the networks have been developed before Decision 2119 came into force, some of them have been funded as concerted actions by DG-Research and some as ad hoc projects by DG-SANCO. The funding mechanism has been subject to rapid, unforeseen changes and has not contributed to coherence in the implementation of the Decision 2119 in the form of surveillance networks. Surveillance systems have an intrinsic basic characteristic as being permanent in nature. Surveillance of communicable diseases is on-going, systematic collection, analysis, interpretation and dissemination of health-related data to those responsible for taking preventive and controlling public health actions. At the EU level, surveillance is particularly targeted at diseases/health issues possibly affecting many Member States at the same time as acute health threats or as a propagating, gradually spreading transmissions. Therefore, a sustainable funding mechanism for core EU-wide surveillance activities is evident.

The development of communicable disease surveillance within the Community network has resulted in a mixture of surveillance activities with differing structures, methods, and outputs between the networks. A framework for evaluating EU-wide surveillance networks was created as a EU funded project (Ruutu et al 2001). In that document, a recommendation to undertake external, independent evaluation of each of the EU-wide surveillance networks at three- to five-yearly intervals was made.

Following the project creating the framework for evaluating EU-wide surveillance networks, EU DG Sanco commissioned an expert group to develop the practical operating procedure, ie methodology, for evaluating an EU-wide disease specific surveillance network (DSN) in the current project (SURVEVAL). The practical evaluation protocol is the main content of this document.

The aim of the evaluation protocol in this document is to provide a standardised tool for the evaluation of EU-wide surveillance networks, addressing the quality of surveillance methods used to obtain potential Community added value (CAV), as assessed by the DSNs and the evaluators, and the timely performance of surveillance activities.

It is proposed that the subject areas identified in this protocol as measuring CAV for EU-wide surveillance would be taken into consideration when the terms of reference is to be constructed for funding surveillance activities for communicable diseases.

3 Background

The overall effectiveness of a DSN relies on the quality of the national surveillance systems and the operational performance of the coordinating hub. Some countries may have no surveillance for a specific disease. National surveillance systems are diverse and they vary in many factors that affect the quality of data. Different case definitions, various reporting activities and systems to submit data from local physician/laboratory level to national and further to international level, country specific differences in health care systems. The Commission has released a Decision on case definitions that should be used for reporting to the Community network (2002/253/EC) thereby trying to minimize the variation due to case definitions. However, the surveillance systems at national level may have a long history and changes in existing systems may be slow and time demanding processes. Appropriate and sufficient resources at national level are essential to strengthen both national and international surveillance.

Another prerequisite for effective international surveillance is sufficient and dedicated staff at the coordinating hub. It may take 3-4 years or even more to develop an international surveillance system that has a potential to provide lasting improvements in national and international surveillance, with true European added value. Therefore, it's essential to identify the development phase of the network and adapt the appropriate indicators to this.

National surveillance systems frequently function in organisations separate from the public health authorities, which are in charge of making decisions on implementing acute control actions or decide on long-term preventive policies. Furthermore, while in the EU the objectives of the DSNs are to provide useful information to the EU and to the national public health officials, the decision making on public health issues in communicable diseases is implemented at the national level. Consequently, it is difficult to measure direct impact of the DSNs on public health. The health impact assessment in terms of changes in population morbidity and mortality is a complex issue and can't be assessed as a result of operation of the DSNs alone. Therefore, the impact assessment in this protocol has been restricted solely to activities traceable to the DSNs.

The future functioning of the Community network is affected by the establishment of the European Centre for Disease Prevention and Control (ECDC).

There has been less than optimal co-operation between the Commission and the Council of European State Epidemiologists (CESE), which incorporates key national competences in supporting the development of optimal methods for EU-wide surveillance on communicable diseases and health issues. To build up a well-functioning link between these essential parties within the Community network, a solid base of knowledge by implementing the external evaluation of the DSNs is needed.

4 Terms of reference

4.1 Legal framework

The DSNs operate under the strand "Responding rapidly an in co-ordinated fashion to Health Threats" of the Public Health Programme (Decision 1786/2002/EC) work plan for 2004. According to the strand, surveillance aims to facilitate and accelerate the co-operation on epidemiological surveillance and control of communicable diseases within the Community network. Priority is to be given to merging networks addressing management with existing resources and to establishing surveillance networks that address priority diseases in an integrated fashion. Unfortunately, the financial rules related to the EU Public Health Programme conflict with essential characteristics of the DSNs, i.e. the need for a stable activity with unchanging, standardised methods over a long period of time.

The Decision 2119/98/EC of the European Parliament and of the Council is the umbrella for surveillance and control activities in the field of communicable diseases. It provides the frames and partly the tools to implement the EU-wide surveillance activities, which consist of the epidemiological surveillance of the diseases and an early warning and response system (EWRS).

The Commission has given the Decision 2000/96/EC on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC. In other words, the decision provides a list of diseases/health issues to be gradually incorporated into EU-wide surveillance. It also defines the criteria for selection of communicable diseases of special areas to be covered by epidemiological surveillance. The priority list has been amended by the Commission Decision 2003/534/EC by adding smallpox, Q-fever and tularaemia on the disease list.

Rapid reaction to acute health threats is covered by the Commission Decision 2000/57/EC on the early warning and response system (EWRS) for the prevention and control of communicable diseases under Decision No 2119/98/EC. The decision provides methods for health threat alerts and rapid responses between designated surveillance authorities. It defines the events to be reported within the EWRS.

The Commission Decision 2002/253/EC lays down case definitions for reporting. These case definitions should be used for reporting to the Community network, which means also reporting to the DSNs. The case definitions enable all Member States to report in a standardised manner as far as possible. The decision has been amended by the Commission decision 2003/534/EC.

The Commission has given an amendment to the Decision No 2000/96/EC as regards the operation of dedicated surveillance networks (2003/542/EC). The decision defines in more details the expected operational elements of the DSNs.

The European Parliament and the Council approved Regulation No 851/2004 for establishing a European center for disease prevention and control (ECDC). A list of central legal documentation is in Annex 1.

4.2 Roles of different parties

Currently, the network for the epidemiological surveillance and control of communicable diseases is managed through the early warning and response system (EWRS) by the competent public health authorities and the technical group as epidemiological surveillance component of the Community network (ESCON) by structures and/or authorities, which are competent and are charged with collecting surveillance information on communicable diseases. Within the evaluation frame, four important parties in the development of the EU-wide dedicated surveillance networks have been recognised.

The Commission provides part of the funding and maintains the legal basis for the existence of the network. The Commission is responsible for implementing decision 2119/98/EC.

The Dedicated Surveillance Network (DSN) in this document means any specific network on diseases or special health issues selected for epidemiological surveillance between accredited structures and authorities of the Member States. It consists of a network of national contact points, which in turn may consist of separate epidemiological and laboratory contact points. Each Member State, through its designated authority, will nominate one contact point (institution, service, department etc.) for each DSN. The contact point is the national representative for providing data and information. Each DSN has a co-ordinating structure, the hub. The hub serves as a technical and scientific co-ordinating unit in the DSN and collects and analyses the data from national level.

The Council of European State Epidemiologists (CESE) forms a pool of national experts who are in charge of and develop the national surveillance systems. Some of the CESE members act as national representatives in the ESCON.

The European Centre for Disease Prevention and Control (ECDC) will have a major role in coordinating the surveillance networks. The Centre may regularly carry out technical and scientific evaluations of prevention and control measures at the Community level.

4.3 Aim and scope of an external evaluation

The aim of this protocol is to provide a standardised tool for the evaluation of EU-wide surveillance networks. The changing legal and organisational environment within the Community network has been taken into account to the extent possible. To avoid duplication of work, the protocol has availed of the existing guidelines for evaluation of surveillance system published by WHO and CDC (Centers for Disease Control and Prevention). The focus has been on identifying the added value from international surveillance implemented at the EU level, defining parameters to evaluate this added value both on the EU and the national level of the Member States, and devising methods for collecting data on these parameters. In the protocol, EU-wide surveillance networks are referred to as "dedicated surveillance networks" (DSNs) in accordance with the Decision 2000/96/EC and its amendment 2003/542/EC.

The overall aim of the evaluation is to assess whether the specific surveillance methodology by the DSNs address in a timely way the epidemiology of diseases/health issues in the European population, and whether the technical performance of surveillance is adequate enough to obtain appropriate level of CAV. The protocol has not been constructed for use in prioritising diseases or disease groups for EU surveillance, which has been the subject of other projects implemented by EU. Even though the practical implementation of the evaluation of a DSN may take place in the context of evaluating several DSNs, this protocol is *not* meant to be used for direct comparison between the DSNs, as the characteristics of the diseases/health issues under surveillance, the methods to reach the EU added value, as well as the resources required vary greatly.

The main emphasis in the evaluation is the effectiveness by which the DSN produces Community added value (CAV) at the European and national level. The evaluation should address and cover the following questions:

- 1. What is the potential added value from the international surveillance for the disease/health issue
- 2. How effectively has the DSN met its potential to provide added public health value?
- 3. What have been the major obstacles preventing the DSN from achieving its potential added value?
- 4. Has the effectiveness of the DSN in meeting its potential added value improved since a previous evaluation?
- 5. What are the recommendations to improve the current situation?

In addition to evaluating the achievement of EU and national added value by the DSN, the evaluation addresses the strengths and weaknesses in operational effectiveness. The DSN needs to achieve an appropriate level of technical performance in order to be able to produce outputs that are needed for meeting the surveillance objectives supporting public health decision making. The evaluation will address both the usefulness of and accessibility to the information outputs. Achieving a sufficient technical performance on the EU level may require substantial developments in the national surveillance systems, which frequently are slow, as they are dependent on the

health care organisation and legal environment in which they work. In the long term, strengthening surveillance systems at the national level through international collaboration improves the effectiveness of international surveillance networks.

International surveillance of communicable diseases at EU level should address one or more of the objectives listed in table1 (Ruutu et al 2001). These objectives are incorporated in the evaluation structure of this protocol for assessing the fulfilment of international added value on the EU level, produced by the DSN. The relative weight of different objectives should be set in advance. This could be based on the work recently done by the expert group in the ESCON¹

Table 1. International surveillance objectives by Ruutu et al (2001).

- 1. Record trends of international importance in the occurrence of disease or in the characteristics of cases
- 2. Ascertain in a timely way cases of public importance, particularly those who are an immediate danger to contacts, in order to permit diagnosis, treatment, and management of contacts, especially when these may be in other countries
- 3. Detect international epidemics or outbreaks, and report national epidemics or outbreaks of international potential
- 4. Support the evaluation of primary and secondary preventive measures that have potential international implications (e.g. population screening or recall of a contaminated foodstuff)
- 5. Contribute to estimates of the relative magnitude of morbidity and mortality due to an infection (disease burden) between different countries
- 6. Monitor the effects of international differences in clinical practice (tertiary prevention), including the use of diagnostic tests and treatment regimes
- 7. Facilitate research in support of prevention or control

5 Rationale for evaluation

The evaluation is based on specific questions reflecting both the CAV and the technical performance of the DSN. The questions have evolved from the legal framework of EU and other relevant Community documentation, existing national or international recommendations on evaluating surveillance systems as applied in the EU context, and a simulated evaluation process covering the data collection tools developed in the current project and proposed to be utilised in the evaluation, as their validation was a limited activity because of the time frame allowed for the project. A full piloting may change the perceptions on how reproducible the responses to data collection forms and, consequently, the parameters for measuring EU added value and technical performance are in a real evaluation context.

Baseline work for prioritising infectious diseases or disease groups, for which it would be most likely to achieve significant EU added value by EU-wide surveillance has been previously done. The results of a prioritisation exercise of likely added valued to be achieved on EU level by Weinberg et al (1999) were incorporated into the Commission Decision of 22 December 1999 (2000/96/EC) on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC. The list covers over 40 diseases/health issues (Annex 1). Experience, which accumulates through the function of the DSNs influences the perceptions of which type of EU added value is actually achievable. At the same time, both the DSNs and national surveillance systems supporting them develop, and this may change the emphasis in what is considered EU added value. Recently, the Commission convened an expert group to advise on improving the reference framework for selecting and financing actions on communicable diseases surveillance (May 2004)¹.

¹ Improving the Reference Framework for selecting and financing actions on communicable disease surveillance, Recommendations of an Expert Group, Final May 2004, 13 pp.

6 Subject areas of an evaluation

An evaluation covers several subject areas, which form the core of the report structure. Each section can be assessed through the checklist (Annex 2), which provides support for qualitative and quantitative assessment of each section. The subject areas are:

- 1) Usefulness of the operation
- 2) Quality of the outputs
- 3) Development of the national surveillance systems
- 4) Technical performance
 - i. Timeliness
 - ii. Quality of data and crude comparability
 - iii. Representativeness
 - iv. Sensitivity and specificity
- 5) Structure and management
 - i. Web site
 - ii. Resources, data protection, and administration
 - iii. Management
 - iv. Decision making
 - v. Costs

The subject areas that are dependent on the specific context, i.e. the changing legal framework and functional responsibilities of the various parties involved, should be reviewed, and the methodology modified, when significant changes take place.

For the results of the evaluation to be valid, and form an appropriate basis for conclusions about the function of a DSN, the evaluation parameters need to be measurable and reproducible by the methodology chosen. A number of the subject areas of technical performance can be measured according to previously published methods (CDC and WHO). As described above in the previous chapter, the direct impact on public health by a surveillance system is usually not possible to measure directly, particularly in international surveillance. However, by collecting data and information from parties responsible for national surveillance, it is possible to build a profile of the usefulness of the DSN, reflecting the actual EU added value achieved, and a view on technical or organisational strengths or obstacles in achieving the targeted added value.

For each subject areas, the evaluation should answer to few larger questions (see chapter 9), which can be assessed through the detailed specific questions in the checklist (Annex 2).

6.1 Measuring Community added value in surveillance

6.1.1 Usefulness of the operation of the DSN (Annex 2, Section 1 and 2)

Usefulness covers an assessment of how the network has succeeded in achieving the objectives addressed in the grant agreement and the international surveillance objectives characteristic for the disease, if these are not well defined in the grant agreement. An analysis of reasons for not achieving the anticipated objectives is of key importance. The hub may have recognised appropriate measures to overcome the obstacles.

The level of agreement between national respondents with different backgrounds (contact points, others) on the fulfilment of relevant international surveillance objectives measures the coherence of perceptions on the usefulness of the activities. A numeric value as Kendall's coefficient of concordance can be calculated.

An analysis of synergies with other surveillance activities already organised in related fields or other organisations, like surveillance mandated by the EU zoonoses directive, WHO and WHO

Europe, relevant joint activities with other Commission departments (like Veterinary Health Services) and other Commission funded projects reflect the complementarity of the DSN activities. All activities aiming at avoidance of duplicate work and fostering the co-operation with other international organisations and with other European agencies (i.e. Eurostat) contribute to added value.

In an action-oriented surveillance network, all public health actions taken or proposed (i.e. international outbreak inquiries, alerts and investigations) should be documented together with an assessment of their outcome or impact, when feasible. It is also of benefit if the DSN recognizes possible health threats or problems in its field and brings them up to a larger attention.

Any concrete surveillance information outputs, which traceably link to improvements in prevention and control policies (i.e. vaccination programmes) or improvements in the laboratory network supporting surveillance, constitutes usefulness of the operation and has the CAV.

The information that a DSN produces should be useful for the Member States. Even if the information has not been traceably used for policy decisions at national level, the relevance of information for the national contact points and key stakeholders are important indicators of added value. Any useful information will remain unused if it is not accessible or it is not distributed in a timely manner. In addition to the national contact points in the network, there is a growing need to provide appropriate datasets of different diseases/health issues for access by the public or research groups.

6.1.2 Development of the national surveillance systems (Annex 2, Section 5)

Any improvements in the capability of the national surveillance systems to support the EU-wide surveillance systems contribute to EU added value. At national level, a change towards completeness of data reporting or a change towards better data quality is of added value. These changes should be addressed in regular data collection by the DSN to the extent feasible, and recorded at the coordinating hub. Significant developments of the national surveillance systems usually require changes either in legislation or the infrastructure and function of the health care delivery system and, consequently, a relatively long time span. The international surveillance networks will have a triggering role in these processes. Therefore, the influence of a DSN on the developments in the national systems may be difficult to trace. Nevertheless, national surveillance systems may collect appropriate minimum agreed data set used by the DSN and thus, fulfil part of the quality of data.

Similarly, some countries may not have a national surveillance system for the specific disease/health issue in the beginning of the DSN function. International expectations may accelerate the building up of a national surveillance system for a disease/health issue. The developments that are traceable to the action of the DSNs will be measured by collecting data from the national contact points on the developments in each of the participating national surveillance systems by diseases/health issues within the EU.

6.1.3 Quality of the outputs (Annex 2, Sections 3 and 4)

The impact of the surveillance information is greatest, when it is actively transmitted directly, in a form appropriate to the key target group(s), to the organisation(s) responsible for decisions on control policies or improvements in surveillance. However, the dissemination of surveillance information may be limited to passive dissemination through academic journals, other publications, websites, and conferences. Through these mechanisms, the information reaches the national surveillance authorities, especially those active in the specific disease/health issue surveillance, but not necessarily the key policy makers. An effort should be made to tailor the information for the

specific authorities responsible for public health policy-making at national and EU level when appropriate.

6.1.3.1 Scientific surveillance report

With few exceptions, a regular scientific report on the surveillance activities is a relevant way of using surveillance data. The content of the scientific report in terms of quality and appropriateness should be assessed. A good report provides an interpretation of the surveillance results with recommendations, if appropriate.

6.1.3.2 Scientific publications

It is of value to know the scientific impact of the DSN in the scientific field. A list of publications that have been produced by the DSN or have been produced using the data of the DSN by other researchers should be available through the website. A list of publications available through general search tools can be used as an additional measurement of data accessibility. Awareness among public health professionals and experts on the DSN and its outputs may also be a relevant measure of visibility.

6.1.3.3 Other documentation

The DSN may provide new guidelines or infection control procedures including laboratory procedures, which are applicable at international and/or national level. The use of these guidelines or procedures at national level reflects their applicability and acceptability.

6.1.4 Technical performance (Annex 2, Section 6)

6.1.4.1 Timeliness

Appropriate timeliness is a key quality indicator for the technical performance of the DSN. It is particularly important for the detection of acute health threats necessitating rapid response. At the EU level, timeliness has two dimensions: incoming data and outgoing information. Timeliness of incoming data refers to delays in submission of data within each country to the national level, and further from national level to the coordinating hub. Timeliness of outgoing information refers to the delays in dissemination of information based on data collection or alerts from the hub. In the frame of timeliness, the nature and effectiveness of the communication link between the hub and appropriate key target groups are important. Appropriate key target groups include designated surveillance authorities at the national and the EU level (see 6.1.3 "Quality of the outputs"). Improvements in timeliness towards what is appropriate in relation to the surveillance objectives are a key prerequisite for achieving the potential added value of the DSN.

A regular communication between the hub and the national contact points, on one hand, and the national centre implementing surveillance for the same diseases/health issues, on the other hand, is essential for bringing information or indications about acute health threats to the attention of the national designated authorities. As important as this is the information flow from national designated surveillance authorities to national contact points especially in case the network performs surveillance on diseases with a potential to cause acute health threats.

6.1.4.2 Quality of data and crude comparability

Crude comparability of data has been listed as a basic indicator for CAV. True comparability of data is not possible to achieve through any simple measurements as it is affected by multiple factors different between the EU countries: health care infrastructures and clinical practice, care seeking behavior of the population together with the availability of health services, surveillance infrastructure and methods, and the legal framework supporting these. All these affect the representativeness, sensitivity and specificity of findings from the surveillance systems in a way that also is different for diseases or disease groups with different characteristics of severity. For comparisons between countries, and to measure the relationship of surveillance data to true disease incidence in the population, population based studies with joint protocols would need to be conducted. The limited parameters available for improving international comparability include defining carefully the properties of the minimum data set, which is needed to collect and analyze relevant data, and to adopt joint case definitions used at national and EU level.

Quality of data is crucial and should be checked already at the national level before reporting to the hub. The hub should check the internal consistency and quality of arriving data before accepting it to the international database. Regular feedback on data quality to the reporting national contact points enhances improvements in reporting.

6.1.4.3 Representativeness

Representativeness forms the basis for comparability of data. Cases notified to a national surveillance system may be derived, e.g. for practical reasons, unevenly from the population, and not be representative of events in the population in general. The data could thus reflect poorly the situation nationally and on the EU level. The evaluation of representativeness should take account the specific objectives of the DSN.

One parameter of representativeness at the EU level is the number of MSs participating in the DSN. However, even if all MSs are participating in the DSN, representativeness may be poor because of poor representativeness of the data within the MSs.

6.1.4.4 Sensitivity and specificity

Sensitivity and specificity of the international surveillance system is mainly dependent on the sensitivity and specificity of the national systems. The availability, patterns of use and quality of laboratory services are the key determinants for the sensitivity and specificity of the national surveillance systems. The quality of national laboratory services can be assessed through participation in external quality assurance schemes (EQA) appropriate for the level of practices in the laboratory. Primary laboratories may participate in EQA schemes for isolation and confirmation of microbe(s) and their antibiotic resistance. Reference level laboratories may participate in EQA schemes for more advanced methodology i.e. serology and molecular microbiology.

6.1.5 Structure and management (Annex 2, Section 7)

Structure and management of the DSN is essential in achieving the operational and surveillance objectives. Basic elements for the successful function of the DSN are the availability and appropriate use of resources (both amount and skills), good administration, careful project management, effective decision making, proper supervision, and secure funding. The Network Committee has endorsed a technical guidance document as regards the operation of dedicated surveillance networks and on-going surveillance projects regarding communicable diseases. This document regulates the relation of the DSN with the Early Warning and Response System (EWRS)

and specifies the tasks of the contact points and the coordinating hub. This relationship may be modified with the establishment of the ECDC.

6.1.5.1 Web site

The web site of the DSN is an effective way for providing information to some target groups. The web sites should be assessed in terms of accessibility to the information and the quality in content of the available information. Web site of DG SANCO should provide a common portal to the DSN web sites.

6.1.5.2 Resources, data protection and administration

The DSN needs appropriate resources for data management, administration, and analytical and epidemiological work. Networks may use appropriate personnel in the hosting institute for the administrative and data management tasks, which is a cost-effective way to share the resources. Administrative issues should not engage a disproportionate proportion of the time of the scientific coordinator. Data management should be implemented according to national and EU data safety regulations. All data transmissions should be organised through appropriate, secure channels ensuring confidentiality of data. The data protection should follow the laws in hosting country.

The network should have a standard operating procedure in place ensuring the confidentiality and priority aspects in case of releasing a data set to a research group outside the network.

6.1.5.3 Management

The Commission has released a document "Project management essentials", which provides general concepts for project management. This document can be applied to the management of the DSN. The main principle is to keep the organisation and the operation of the DSN as simple as possible. In the beginning, the time should be allowed to build up the infrastructure and operation starting with the collection and analysis of a relevant minimum data set. Once the structure and operation have reached the anticipated level, the network could enlarge to new diseases/health issues given that the objectives have been clearly redefined and appropriate resources are allocated to the project. A good, properly documented project management process shows the different phases of development and regularly internally reviews the achievements. The project management should ensure that the funds are used effectively and the achievements gained should be monitored and documented. In order to enhance the acceptability by the participants, the DSN should have a regular communication culture between the hub and the contact points. The DSN should also monitor the usefulness of annual meetings.

The continuity of the hub workers, especially the scientific coordinator, is essential for the continuous and undisturbed operation of the DSN.

6.1.5.4 Decision making

The decision making process of the DSN should be effective and transparent, and include a regular review of the implementation status of previous decisions. Each DSN should have an advisory board or a similar structure, with the aim of securing diverse expertise in decision making. This supervisory body provides an appropriate base for strategic decision making in the DSN. The implementation and the outcome of decisions should be monitored.

6.1.5.5 Costs

The cost-effectiveness of an international surveillance system is not possible to evaluate in this context, as the measurable control actions or policy decisions that should follow from surveillance information are usually dependent on decision making by parties other than the surveillance organisation, and frequently depend on inputs from several sources. The costs are, therefore, only dealt with in identifying funding constraints or less than optimal usage of the available resources, which may be limiting factors in fulfilment of the objectives of the DSN.

7 Practical implementation of an evaluation

7.1 Proposed use of the protocol

The protocol has been prepared in a format of external evaluation by a third, independent party. The evaluation is targeted at *the preceding 3 years of activity* of the DSN. However, the tools are easily adaptable to other time frames also.

The data for evaluation should be collected at least from the coordinating hub, external key stakeholders including particularly the State Epidemiologists for Infectious Disease, and national contact points in the DSN. The data collection forms for the evaluation have been constructed specifically for these target groups. However, other groups may be included in the data collection for evaluation depending on the needs and specific aims of the evaluation. Other target groups might be advisory board members, public health professionals, and the public.

In addition to identifying ways for developing the effectiveness of the DSN, the results of the evaluations can be used to support the decision making for funding the surveillance networks further.

7.2 Evaluation team

The external evaluation team needs to have appropriate expertise in the field of public health. There should be no linkage of the evaluators to the DSN under evaluation. For example, an active role in the DSN or employment at the institute hosting the DSN would be considered too close a linkage for an evaluator.

The suggested evaluation team consists of three persons: one senior expert with appropriate, e.g. at least 5 - 10 years, of experience in surveillance on communicable diseases in the EU context, one expert in public health, and one junior expert, e.g. a trainee in a field epidemiology training program or a post graduate fellow in epidemiology, who would act as a scientific secretary of the team. If possible, the senior team members should come from different countries.

7.3 Steps of the evaluation

The suggested evaluation steps are as follows:

- a. Contracting the evaluating team by EU
- b. Planning meeting of the evaluation team, adoption of detailed evaluation methods
- c. Inventory of existing documentation on the DSN
- d. Questionnaires to the external key stakeholders and national epidemiology and laboratory contact points
- e. Questionnaire to the hub scientific coordinator
- f. Visit to the hub with interview of the key DSN personnel
- g. Analysis of collected information

- h. Preliminary report with major and minor findings and recommendations
- i. DSN response to the findings
- j. Final report with recommendations to the EU
- k. Informing the ESCON

It is preliminarily estimated that the two senior experts would spend 2 (team leader) and 4 weeks (expert member) as full time equivalents, respectively, in the evaluation. The junior expert, e.g. a trainee in a field epidemiology training program or a post graduate fellow in epidemiology, would work the full time equivalent of 2-3 months as the secretary of the evaluation team.

All relevant documentation regarding the structures, management, outputs and activities of the DSN should be available for the evaluation team. Below is a list of possible documents to be asked from the hub in advance:

- 1. Annual surveillance reports of past 3 years
- 2. List of publications produced by the DSN or with a co-writer from the staff or the national contact points of the DSN
- 3. List of hub workers, national epidemiology and laboratory contact points, and advisory board members
- 4. Grant agreement for the preceding 3 years
- 5. Documents produced by the DSN for national use; protocols, guidelines, procedures etc. including case definition(s) and minimum agreed data set(s)
- 6. Documents produced by the DSN for internal use as standard operating procedures
- 7. Minutes of the advisory committee meetings from the preceding 3 years
- 8. Former evaluations, if any

In addition to the documentation available, the web site of the DSN should be assessed.

National contact points form a pool of active network members, involved in the practical implementation of the DSN operations, and are an important source of structured information for the evaluation. The DSN may have performed internal surveys on its functions, which may have covered partially the data included in the forms developed for the external evaluation. Data from these internal surveys should be exploited, and an effort should be made to avoid duplicate work in the external evaluation. Separate questionnaires should be used for the national epidemiological and the laboratory contact points, where the DSN has both of these. Annexes 4 (epidemiology) and 5 (laboratory) are examples of the questionnaires that are proposed for collecting relevant data from the national contact points. If the DSN is organised to have only one contact point in each country, the form in Annex 4 (epidemiology) should be used with appropriate modifications. If the DSN covers more than one disease/health issue, for each of which there is a separate national epidemiology contact point, each of these named contact points should fill a form for the disease/health issue they are responsible for as a national contact point. The form proposed for data collection from the key national stakeholders, usually the State Epidemiologists for infectious diseases, is in Annex 6.

Collection of information from the hub, in addition to the existing DSN documentation, is implemented as a structured interview at the coordinating hub. Annex 3 is the proposed structure for the interview. It should be sent to the hub well before the visit. It is useful to fill certain questions, e.g. question 2.1 according to the specific terms of reference of the DSN, prior to the interview visit. During the interview of the scientific coordinator, the questionnaire that was sent to the hub earlier is completed.

Data items for measurement of the same parameters are collected on one or, in many instances, several forms. As an intermediate step for bridging collection of data and other types of information to verbal conclusions, parameters measuring different areas of performance have been grouped together in a proposed checklist form (Annex 2). It provides detailed examples on how to combine

and assess the collected data. The team of surveillance experts may freely adapt the proposed documentation according to their views and needs. The proposed tools for data collection can be revised according to the possible tailored needs in the evaluation. However, a standardised documentation is a prerequisite for comparing the results of subsequent evaluations on the same DSN and the fulfilment of previous recommendations.

8 Analysis

The data and information used for analysing the performance of the DSN in various subject areas listed in chapter 6 derive from pre-existing DSN documentation, structured interview of the hub personnel, questionnaire responses by State Epidemiologists for infectious diseases, 25 national epidemiology contact points, and 25 national laboratory contact points (if nominated separately). Based on this, the evaluation team will build a profile of the effectiveness of the function of the DSN in each of the subject areas of evaluation parameters.

It is essential that the structure of the analysis phase focuses at answering the few specific questions in each section (see chapter 9). The checklist form (Annex 2) has been structured to make the use of information on a specific subject area from different sources more efficient. Each section should conclude with a synthesis of major and minor findings both for strengths and weaknesses based on their ability to support or hamper the fulfilment of the objectives. Major weaknesses require urgent action by the DSN. Based on the findings, the effectiveness of the function of the DSN in each section may be assessed by a three-level rating from high to low. However, the checklist should not restrict the analysis of data from methods preferred by experienced surveillance experts.

9 Reporting and recommendations

The reporting structure is based on subject areas (see chapter 6), which have been assessed by support of the checklist. The overall synthesis of conclusions should incorporate statements responding to each of the questions listed under subject areas, and make clear recommendations both to the DSN and to the EU administrative organisation responsible for funding of the DSN. These recommendations need to take into consideration the changing EU legal and organisational environment to guide decision making.

The preliminary report should be sent to the DSN. The DSN should check the report, identify possible inaccuracies, and agree with the findings or make statement of disagreement on an issue, for which it considers it justified. Corrections are made on issues on which both the evaluating team and the DSN agree. An issue of clear disagreement is recorded in the final report.

9.1 Evaluation of the usefulness of the operation of the DSN

- 1) How has the DSN met their anticipated objectives?
- 2) How has the DSN contributed to rapid detection of health alerts, if relevant?
- 3) How is the DSN addressing synergy with already existing projects in the same area?
- 4) To what extent has the DSN contributed to health protection and/or improvement of public health?
- 5) What is the internal level of coherence in perceptions on the importance/usefulness of the activities/outputs?

9.2 Evaluation of development of the national surveillance systems

- 1) How have the national systems improved in time for the surveillance of the disease(s)/health issues?
- 2) Are any of these improvements traceable to the operation of the DSN?

- 3) Has the DSN supported the development of national surveillance systems in a concrete manner? How?
- 4) How coherent are the annual incidences between the DSN database and the national official data?
- 5) What is the effect of the difference in annual incidences, if any, on the quality of surveillance results regarding the fulfilment of the objectives?
- 6) What benefits have the Member States achieved through outputs or participating in the operation of the DSN?

9.3 Evaluation of the quality of the outputs

- 1) Has the DSN provided a scientific surveillance report that covers all diseases/health issues under surveillance?
- 2) Has the DSN recognised the key target groups for the information?
- 3) Has the DSN provided interpretations and recommendations of the surveillance results, if appropriate?
- 4) Has the dissemination of the information been appropriate regarding timeliness, target groups, and accessibility to the information?
- 5) Has the DSN produced other publications based on the produced information or activity of the network?
- 6) Is the list of publications (produced by the DSN) available through the website?
- 7) Has the DSN produced relevant documents for internal or national use?

9.4 Evaluation of technical performance

9.4.1 Timeliness

- 1. Has the network defined the time frame within which the national data are to be delivered to be appropriate with its specific surveillance objectives?
- 2. Is the timeliness of outgoing information appropriate for the objectives of the DSN?
- 3. How is the communication between the DSN and the national surveillance centre?
- 4. How has the timeliness of data inflow and outflow improved in time?

9.4.2 Quality of data and comparability

- 1) How compatible is/are the case definitions of the DSN with the EU case definitions and what is the effect of variation on the activity of the DSN?
- 2) Is the minimum data set appropriate in terms of objectives?
- 3) Has the data quality been checked at appropriate levels?
- 4) How are the differences between annual incidences in national databases and DSN databases explained?

9.4.3 Representativeness

- 1) How is the DSN addressing the problem of representativeness?
- 2) What is the coverage of Member States participating in the DSN?

9.4.4 Sensitivity and specificity

- 1) Have the national and reference laboratories participated in appropriate EQA schemes?
- 2) How has the hub taken into account the sensitivity and specificity?

9.5 Evaluation of structure and management

9.5.1 Web site, resources, data protection and administration

- 1) How does the web site provide information in terms of appropriateness, accessibility to and timely distribution of information
- 2) Are the resources used effectively?
- 3) Has the confidentiality of data management fulfilled the EU regulations?

9.5.2 Management

- 1) How has the project management developed in time?
- 2) Does the DSN communicate effectively with the national contact points?
- 3) Has the DSN developed any standard operating procedures for internal use?
- 4) Has the DSN secured its continuity in the longer absence of personnel?

9.5.3 Decision making

- 1) Is the decision making effective and the follow-up of implementation appropriately monitored?
- 2) Are the national contact points satisfied with the decision making?

9.5.4 Costs

- 1) Have the funds been sufficient to fulfil the objectives of the DSN?
- 2) Have the sub-contracting arrangements been satisfactory at national
- 3) Have the sub-contracting arrangements been satisfactory at EU level?

9.6 Recommendations

The result of the evaluation is a final report to be brought to the attention of DG Sanco, the Community network, the DSN coordinating hub, as well as the national centres participating in the DSN.

The report should include recommendations on the appropriateness of funding by EU, to be incorporated in the decision making of the ongoing EU contracting process on the DSNs, as well as on possibly identified problems in the function of the DSN central coordinating hub, its relationship with the hosting organisation, or the national surveillance systems supporting the DSN. Decisions for implementing the recommendations are made by the appropriate parties, i.e. DG Sanco, the European Centre for Disease Prevention and Control as defined in its future procedural documents, DSN coordinating hub, organisation hosting the DSN hub, and the Member States.

References

Centers for Disease Control and Prevention. Updated guidelines for evaluating public health surveillance systems: recommendations from the guidelines working group. MMWR 2001;50 (No. RR-13):[1-36].

Commission Decision of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (2000/96/EC)

Commission Decision of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council (2000/57/EC)

Commission Decision of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (2002/253/EC)

Commission Decision of 17 July 2003 amending Decision No 2000/96/EC as regards the operation of dedicated surveillance networks (2003/542/EC)

Commission Decision of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases (2003/534/EC)

Communication to the Commission, Community action in the field of Public Health (2003 to 2008) – Work Plan 2004.

Consultation Paper on Centre for Disease Prevention Control. High Level Committee on Health, Meeting Elsinore, 17.-18.12.2002, registration No HLHC/2002/3/5

Corrigendum to Commission Decision 2003/542/EC of 17 July 2003 amending Decision 2000/96/EC as regards the operation of dedicated surveillance network (OJ L 185 of 24.7.2003)

Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

Decision No 1719/1999/EC of the European Parliament and of the Council of 12 July 1999 on a series of guidelines, including the identification of projects of common interest, for trans-European networks for the electronic interchange of data between administrations (IDA)

Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008)

Development of Surveillance and Control of Communicable Diseases in the European Union 2003-2008. Prepared by the CESE group for the European Commission DG SANCO, March 2002.

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC.

Draft Commission Decision G4/WD 84/V3 on disease specific networks and procedures for information exchange regarding communicable diseases in the context of the Community network under Decision No 2119/98/EC of the European Parliament and of the Council.

Draft memorandum of understanding for the implementation of a European concerted research action designated as COST Action 920 "Foodborne Zoonoses: a Coordinated Food Chain Approach", European Cooperation in the field of Scientific and Technical Research, COST 253/01, DG C III, Brussels, 19 June 2001.

Draft: Proposal for a regulation of the European Parliament and of the Council (30 May 2003) establishing a European Centre [for Disease Prevention and Control] [ECDPC]

Economisti Associati SRL. Establishing an evaluation process for the European Commission public health program. SANCO/2002/G1/001. Final report, vol II. Program indicators, July 10, 2003.

EN ISO/IEC 17025:2000, General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:1999).

Improving the Reference Framework for selecting and financing actions on communicable disease surveillance. Recommendations of an Expert Group, Final May 2004, 13 pp.

Memorandum of Understanding concerning co-operation between the Commission of the European Communities and the European Co-operation for Accreditation in the field of conformity assessment, 2.6.1999.

Progress report on the network for the epidemiological surveillance and control of communicable diseases in the community. Commission of the European communities, Brussels, 7.9.2000, COM(2000) 471 final

Project management essentials, European Commission, Office:EUFO 4/270. Tel. (352) 43 01-32 719.

Protocol for the assessment of national communicable disease surveillance and response systems: guidelines for assessment teams, 2001. WHO, Department of Communicable Disease Surveillance and Response. WHO/CDS/CSR/ISR/2001.2.

Protocol for the Evaluation of Epidemiological Surveillance Systems. 1997, WHO, Division of Emerging and other Communicable Diseases Surveillance and Control. WHO/EMC/DIS/97.2.

Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the community institutions and bodies and on the free movement of such data.

Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents.

Regulation of the European Parliament and of the Council Establishing a European Centre [for Disease Prevention and Control], Brussels, 16.9.2003, COM(2003) 441 final/2, 2003/0174 (COD).

Regulation (EC) of the European Parliament and of the Council of April 2004 establishing a European centre for disease prevention and control. OJ L 142, 30.4.2004, p.1

Ruutu P, Breuer T, Desenclos J-C, Fisher I, Giesecke J, Gill N, Infuso A, Salmaso S & Tegnell A. A framework and recommendations for evaluating surveillance systems within the community network for communicable diseases, Basic Network for Surveillance of Infectious Diseases in European Union, report for European Commission: Directorate General Health & Consumer protection, 21.02.2001.

Strengthening Europe's defences against health threats: Commission proposes European Centre for Disease Prevention and Control. Press release IP/03/1091, Brussels, 23 July 2003

Technical guidance document as regards the operation of dedicated surveillance networks and ongoing surveillance projects regarding communicable diseases in the context of the Community Network (Decision 2119/98/EC of the European Parliament and the Council and Decision 2000/96/EC), WD 110/v2-final.

Treaty establishing the European Community, 25.3.1957.

Weinberg J., Grimaud O., Newton L & the Charter Group. Establishing priorities for European collaboration in communicable disease surveillance. Eur J Public Health 1999; 9: 236-240.

WHO Recommended Surveillance Standards. 1999. WHO, Department of Communicable Disease Surveillance and Response. WHO/CDS/CSR/ISR/99.2.

WHO-recommended standards for surveillance of selected vaccine-preventable diseases. Vaccines and Biologicals, WHO/V&B/03.01, February 2003.

Annex 1: Central legal documentation

1 (3)

1. Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, amended by the Commission Decision 2003/534/EC

List of categories of communicable diseases in Annex:

- 1. Diseases preventable by vaccination
- 2. Sexually-transmitted diseases
- 3. Viral hepatitis
- 4. Food-borne diseases
- 5. Water-borne diseases and diseases of environmental origin
- 6. Nosocomial infections
- 7. Other diseases transmissible by non-conventional agents (including Creutzfeldt-Jakob's disease)
- 8. Diseases covered by the international health regulations (yellow fever, cholera and plague)
- 9. Other = other diseases (rabies, typhus, viral haemorrhagic fevers, malaria and any other as yet unclassified serious epidemic disease, including diseases that are caused by agents specifically engineered for the purpose of maximising morbidity and/or mortality upon deliberate release, etc.)
- 2. Commission Decision of 22 December 1999 (2000/96/EC) on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, amended by the Commission Decision 2003/542/EC and 2003/534/EC.

Annex I: Communicable diseases and special health issues to be progressively covered by the Community network:

- 1. Diseases preventable by vaccination
 - a. Diphtheria
 - b. Infections with *Haemophilus influenza* group B (*)¹
 - c. Influenza (*)
 - d. Measles (*)
 - e. Mumps
 - f. Pertussis (*)
 - g. Poliomyelitis
 - h. Rubella
 - i. Smallpox
 - j. Tetanus
- 2. Sexually -transmitted diseases
 - a. Chlamydia infections
 - b. Gonococcal infections
 - c. HIV-infection (*)
 - d. Syphilis
- 3. Viral hepatitis
 - a. Hepatitis A
 - b. Hepatitis B
 - c. Hepatitis C
- 4. Food- and water-borne diseases and diseases of environmental origin
 - a. Anthrax
 - b. Botulism

¹ (*) Those communicable diseases and special health issues for which a dedicated surveillance network is in place (Commission Decision 2003/542/EC)

Annex 1: Central legal documentation

2 (3)

- c. Campylobacteriosis
- d. Cryptosporidiosis
- e. Giardiasis
- f. Infection with Enterohaemorrhagic E. coli (*)
- g. Leprospirosis
- h. Listeriosis
- i. Salmonellosis
- j. Shigellosis
- k. Toxoplasmosis
- I. Trichinosis
- m. Yersiniosis
- 5. Diseases transmitted by non-conventional agents
 - a. Transmissible spongiform encephalopathies, variant Creutzfeld-Jakob's disease (*)
- 6. Air-borne diseases
 - a. Legionellosis (*)
 - b. Meningococcal disease (*)
 - c. Pneumococcal infections
 - d. Tuberculosis (*)
- 7. Zoonoses (other than those listed in 4.)
 - a. Brucellosis
 - b. Echinococcosis
 - c. Rabies
 - d. Q-fever
 - e. Tularaemia
- 8. Serious imported diseases
 - a. Cholera
 - b. Malaria
 - c. Plague
 - d. Viral haemorrhagic fevers
- 9. Nosocomial infections
- 10. Antimicrobial resistance $(*)^2$

Annex II: Criteria for selection of communicable diseases of special areas to be covered by epidemiological surveillance within the network:

- 1. Diseases that cause, or have a potential to cause, significant morbidity and/or mortality across the Community, especially where the prevention of the disease requires a global approach to coordination
- Diseases where exchange of information may provide early warning of threats to public health
 Rare and serious diseases which would not be recognised at national level and where pooling of data would allow hypothesis generation from a wider knowledge base
- 4. Diseases for which effective preventive measures are available with a protective health gain
- 5. Diseases fro which a comparison by Member States would contribute to the evaluation of national and Community programmes

Annex III (Commission Decision 2003/542/EC): Topics to be addressed by operating procedures of dedicated surveillance networks to be submitted to the Community network:

- 1. Coordinating structure and decision making process
- 2. Project management administration and supervision
- 3. Case definitions, nature, and type of data to be collected

² (*)Those communicable diseases and special health issues for which a dedicated surveillance network is in place (Commission Decision 2003/542/EC)

Annex 1: Central legal documentation

3 (3)

- 4. Data management and protection, including data access and confidentiality
- 5. Ways in which data are made comparable and compatible (quality requirements and data validation)
- 6. Appropriate technical means and the procedures by which the data are to be disseminated and analysed at Community level (data dissemination and reporting)
- 7. Proposed public health action, infection control procedures, and laboratory procedures
- 3. Commission Decision of 22 December 1999 (2000/57/EC) on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council. The Decision defines the events to be reported within the EWRS:
 - 1. Outbreaks of communicable diseases extending to more than one Member State of the Community
 - 2. Spatial or temporal clustering of cases of disease of a similar type, if pathogenic agents are a possible cause and there is a risk of propagation between Member States within the Community
 - 3. Spatial or temporal clustering of cases of disease of a similar type outside the Community, if pathogenic agents are a possible cause and there is a risk of propagation to the Community
 - 4. The appearance or resurgence of a communicable disease or an infectious agent which may require timely, coordinated Community action to contain it.
- 4. Commission Decision of March 2002 (2002/253/EC) laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council
- 5. Commission Decision of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases (2003/534/EC)
- 6. Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008)
- Proposal for a regulation of the European Parliament and of the Council establishing a European Centre [for Disease Prevention and Control], Brussels, 16.9.2003, COM(2003) 441 final/2
- 8. Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the community institutions and bodies and on the free movement of such data
- 9. Regulation (EC) of the European Parliament and of the Council of April 2004 establishing a European centre for disease prevention and control. OJ L 142, 30.4.2004, p.1

1. USEFULNESS	OF THE OPERATION	DSN:	Date of evaluation: /		
Source of data	Check questions	Asses	sment	Remarks	
		Target	Developing		
<i>Meeting the objectives</i> Annex 3, 1.1	Has the hub fulfilled the objectives it has stated in the grant agreement?	🗌 Yes, all	☐ Yes, partly ☐ No	Describe which objectives han not.	we been fulfilled and which
Annex 3, 1.3	Has the hub recognized the major obstacles in not achieving the anticipated objectives or deliverables?	🗌 Yes	🗌 No	Describe the major obstacles See also section 7; costs.	3
Annex 3, 1.4	Has the hub recognized appropriate measures to overcome the obstacles?	🗌 Yes	🗌 No	Describe the measures the h fulfilment of objectives	ub plans for improving the
Alerts and	Has the hub made inquiries to national level	☐ Yes; t	imes		mean any inquiries made to
<i>collaboratorion</i> Annex 3, 2.1	due to alerts evolving from the operation of the DSN?	☐ Not relevant	🗌 No	national contact points regarding potential health threats recognized at the hub.	
Annex 3, 2.2	Has the hub monitored the outcome of the inquiries	☐ Yes ☐ Not relevant	☐ Yes, partly ☐ No	"Yes" means that the hub (document) the outcome of	
Annex 3, 2.3	Has the DSN provided expertise for international outbreak investigations?	☐ Yes ☐ Not relevant	🗌 No	"No" means that the objective outbreak detection and, poter expertise for international out case, explain why the answer	ntially, involvement in providing break investigations. In that
Annex 3, 2.4	Has the DSN informed the national contact	☐ Yes, ti	mes		
	points about potential acute health threats?	Not relevant	🗌 No		
Annex 3, 2.5	Has the DSN set up any public health actions or infection control procedures to be taken at the DSN level based on the results of the surveillance?	☐ Yes ☐ Not relevant	🗌 No	If the procedures are relevent objectives of the DSN the	

1. USEFULNESS (OF THE OPERATION	DSN:	Date of evaluation: /		
Source of data	Check questions	Assess	sment	Remarks	
		Target	Developing		
Annex 3, 2.6	Has the DSN co-operation with relevant parties regarding the objectives?	🗌 Yes	🗌 No		
Benefits for the MSs Annex 4, 2.1 Annex 6, 2.1	Has the operation led to immediate public health interventions (e.g. outbreak investigations) in Member States?	☐ Yes ☐ Not relevant	🗌 No	If Yes, specify the interver MSs reporting interventior	
Annex 4, 2.2 Annex 6, 2.2	Has the operation led to any improvements in prevention and control policies (i.e. vaccination programmes)	☐ Yes ☐ Not relevant	🗌 No	If Yes, specify the improve MSs reporting improveme	ements and the number of nts
Annex 5, 2.1 Annex 6, 2.4	Has the operation produced benefits for the MSs and the national laboratory network including reference level laboratory?	🗌 Yes	🗌 No	If Yes, specify the benefits	3
Annex 4, 4.1 Annex 5, 4.1	Does the DSN produce and report the MSs more detailed analysis or information than is regularly produced and reported at national levels?	🗌 Yes	□ No □ Don't know	Describe and assess the	results.
Annex 4, 4.2 Annex 5, 4.2 Annex 6, 3.1	Have the MSs used any documents (other than scientific surveillance report) produced by the DSN if any?	☐ Yes ☐ Not relevant	🗌 No	Describe and assess the documents	esults by available
Annex 4, 4.3 Annex 5, 4.3 Annex 6, 3.1	Have the MSs used the information provided in scientific surveillance report if any?	🗌 Yes	□ No □ Not relevant	Describe and assess the produce a scientific surve	
Annex 4, 4.4 Annex 5, 4.4 Annex 6, 3.2	How important is the produced information for the national contact points? How useful has the information produced been for key stakeholder(s)	Charts		Describe and assess the	results.

1. USEFULNESS (OF THE OPERATION		DSN:	Date of evaluation: /		
Source of data	Check questions		Assess	sment	Remarks	
		Target Dev		Developing		
Major strengths:		Major	weaknesses:			
Minor strengths:			Mino	weaknesses:		
The overall impression of the evaluation team on the performance regarding the usefulness of the operation		🗌 Hig	h	Medium	Low	

2. USEFULNESS O SURVEILLANCE O	F THE OPERATION; AGREEMENT ON GEI BJECTIVES	DSN:	Date of evaluation: /		
Sources of data; Annex 4, 1.2		Re	plies	Remarks	
	Annex 5, 2.6 Annex 6, 2.5	Not relevant	Rate		
a) Record trends of international importance in the occurrence of disease or in the characteristics of cases		by the hub / national epidemiology contact points	by the hub median of replied national epidemiology contact points	"not relevant" –replies (% epidemiology contact poir State Epidemiologists for Compare the rate by the h the national epidemiology range of values of national	nt" -reply by the hub and the 6) by the national nts. Make comparison with Infectious Diseases as well. nub to the median of rates by contact points. Consider the al replies. Make comparison s for Infectious Diseases as
				Calculate Kendall's coeffic appropriate	cient of concordance, if
particularly those w order to permit diag	nely way cases of public importance, who are an immediate danger to contacts, in gnosis, treatment, and management of y when these may be in other countries	by the hub hub hational epidemiology contact points	by the hub mean of replied national epidemiology contact points		
c) Detect international epidemics or outbreaks, and report national epidemics or outbreaks of international potential		by the hub hub hational epidemiology contact points	by the hub mean of replied national epidemiology contact points		
measures that have	luation of primary and secondary preventive e potential international implications (e.g. ng or recall of a contaminated foodstuff)	by the hub hub hational epidemiology contact points	by the hub mean of replied national epidemiology contact points		

2. USEFULNESS OF THE OPERATION; AGREEMENT ON GENERIC INTERNATIONAL SURVEILLANCE OBJECTIVES						Dat	te of evaluation: /
Sources of data;	Annex 4, 1.2		Re	olies	Remarks		
	Annex 5, 2.6 Annex 6, 2.5	Not rele	vant	Rate			
		by the h	nub	by the hub			
e) Contribute to estimates of the relative magnitude of morbidity and mortality due to an infection (disease burden) between different countries		national epidemiolo contact po	0,	mean of replied national epidemiology contact points			
		by the h	nub	by the hub			
practice (tertiary pre	 f) Monitor the effects of international differences in clinical practice (tertiary prevention), including the use of diagnostic tests and treatment regimes 		gy ints	mean of replied national epidemiology contact points			
		by the I	nub	by the hub			
g) Facilitate research in support of prevention or control		national epidemiology contact points		mean of replied national epidemiology contact points			
Assess the fulfilment of the international objectives in terms of compatibility with the DSN surveillance objectives							
	on of the evaluation team on the performance ic international surveillance objectives	e for the	🗌 Hig	h	Medium		Low

3. QUALITY OF T	HE SURVEILLANCE REPORTS	DSN:	Date of evaluation: /			
Source of data	Check questions	Assess	sment	Remarks		
		Target	Development			
Annex 3, 3.1 Review	Has the DSN produced surveillance report(s)	🗌 Yes	🗌 No	Explain why not.		
Annex 3, 3.1 Review	Do the surveillance reports cover all diseases/health issues under surveillance?	☐ Yes	🗌 No	Check through the available diseases/health issues that	reports and specify the are not covered in the reports.	
Annex 3, 3.2 Review	Has the hub recognized the key target groups for the reports?	☐ Yes	🗌 No	The key target groups could be the State Epidemiologists and the national surveillance authorities.		
Annex 3, 3.3 Review	Are the surveillance reports available through the web site?	🗌 Yes	□ No	The web site provides the ea the reports	asiest and quickest access to	
Annex 3, 3.3	Does the hub send the reports actively to the national surveillance authorities?	☐ Yes	🗌 No	The reports should be sent actively to the national surveillance authorities who are responsible for the surveillance of the disease(s)/health issues in their own countries		
Annex 3, 3.1 Annex 3, 3.2 Annex 3, 3.3	Does the hub send a summary or a short report to the Commission addressing important issues at the Community level that have arisen through the surveillance?	☐ Yes	□ No			
Annex 3, 3.4	Has the DSN specified a surveillance report time interval?	🗌 Yes	🗌 No	A surveillance report shou predefined interval.	ld be produced at	
Annex 3, 3.4	Is the reporting time appropriate regarding the objectives?	🗌 Yes	🗌 No	Explain why not		

3. QUALITY OF TH	E SURVEILLANCE REPORTS	DSN:	Date of evaluation: /			
Source of data	Check questions		Assess	ment	Remarks	
		Target Deve		Development		
Surveillance reports	Does the hub provide an interpretation of the surveillance results in the surveillance reports?	□ Yes		🗌 No		
Surveillance reports Annex 3, 3.5	Are the interpretations appropriate regarding the objectives of the DSN?	☐ Yes		🗌 No	Explain why not. What difficulties exist in interpretation of the results?	
Surveillance reports	Has the hub provided any recommendations in the surveillance reports?	☐ Yes		🗌 No	Explain why not	
Major strengths:			Major v	veaknesses:		
Minor strengths:			Minor	weaknesses:		
The overall impression of the evaluation team on the performance for the quality of the surveillance reports			🗌 High		🗌 Medium	Low

4. QUALITY OF O	THER OUTPUTS	DSN:	Date of evaluation: /			
Source of data	Check questions		Assess	sment	Remarks	
		Target		Development		
Review Annex 3, 4.1	Has the DSN published any articles in peer reviewed journals based on data collected by the DSN?	☐ Yes; articles		🗌 No		
Annex 3, 4.2 Review	How many of these articles has a co-writer from the DSN?	🗌 All		1	The co-writer can be any of the national contact points of the DSN as well. All articles that are published based on collected data should have at least one co-writer from the DSN.	
Annex 3, 4.3 Review	Has the DSN produced any standard operating procedures or guidelines for the national level?	☐ Yes ☐ Not i	relevant	🗌 No	List and describe the docum contact points whether they not (see section 1).	ents. Check from national have used the documents or
Annex 3, 4.4	Are these guidelines available for the national contact points through the web site?	□ Yes		🗌 No	Web site is recommended	I.
Major strengths:	Major strengths:			veaknesses:		
Minor strengths:			Minor	weaknesses:		
The overall impression of the evaluation team on the performance for the quality and appropriateness of other outputs (than surveillance report).			🗌 High		Medium	Low

5. DEVELOPMEN	T OF THE NATIONAL SURVEILLANCE SYSTE	DSN:				
Source of data Check questions			Assess	ment	Remarks	
		Tar	get	Development		
Annex 3, 4.1	Has the quality of submission of national data to the DSN improved in time?	🗌 Yes		🗌 No	Describe, how has the qualit improved.	y of data submission
Annex 3, 4.2 Review	Have the Member States improved the completeness of data in terms of minimum agreed data set?		☐ Yes; / MSs ☐ No ☐ Don't know			
Annex 3, 4.3	Has the hub provided concrete support for the development of the national surveillance systems?	☐ Yes ☐ Not relevant		🗌 No	Describe how	
Annex 4, 3.1 Annex 5, 3.1 Annex 5, 3.3 Annex 6, 2.3	Has the operation led to any improvements in the laboratory networks related to surveillance in MSs?	☐ Yes ☐ Not relevant		☐ No ☐ Don't know	Describe and assess the results. Specify the improvements and the number of MSs reporting improvements	
Annex 5, 3.2	Has the operation led to any improvements in protocols or procedures for taking specimens?	🗌 Yes		☐ No ☐ Don't know	Describe and assess the improvements and the nu improvements.	
Annex 4, 3.4 Annex 5, 3.8	Do the annual incidences differ between the national officially reported data and the data submitted to the DSN?	☐ Yes ☐ Not r	elevant	🗌 No	Assess the explanations by contact points	epidemiology and laboratory
Major strengths:			Major v	veaknesses:		
Minor strengths:			Minor v	veaknesses:		
	sion of the evaluation team on the performance f e national surveillance systems	or the	the High		🗌 Medium	Low

6. TECHNICAL P	ERFORMANCE	DSN: Date of evaluation				
Source of data	Check questions	sment	Remarks	•		
		Target	Development			
<i>Timeliness</i> Annex 3, 5.1	Does the hub monitor the delays in reporting from the national level to the hub by countries?	☐ Yes	🗌 No			
Annex 3, 5.2 Annex 3, 5.3	Has the timeliness of data submission by national contact points improved in time?	☐ Yes	🗌 No	Explain what have been the major obstacles in submission of data.		
Annex 3, 5.4	Has the timeliness of surveillance reporting by the hub improved in time?	Yes Not relevant	□ No			
Website	When was the last update of the website?			Assess the appropriate for activities	ness regarding the timeliness	
<i>Comparability</i> Annex 3, 5.10	Has the hub addressed the comparability of data between the MSs appropriately regarding the objectives?	☐ Yes ☐ Not relevant	🗌 No	Explain how. Explain w	hy not, if relevant.	
Annex 4, 3.4 Annex 5, 3.8	What reasons exist for possible variation in annual incidences between the data reported by the DSN and the official data published by the MSs?				rms of effect on comparability r corrective actions could be	
Review	Is the minimum data set appropriate in terms of the objectives of the DSN?	🗌 Yes	🗌 No	Explain why not.		

6. TECHNICAL PE	ERFORMANCE	DSN:	Date of evaluation: /			
Source of data	Check questions	Assess	Assessment			
		Target	Development			
Annex 3, 5.7 Annex 4, 3.5 Annex 4, 3.6	Is/are the case definition(s) of the DSN compatible with the EU case definition?	☐ Yes	🗌 No		Explain the differences and assess their impact on effectiveness of surveillance	
Annex 3, 5.8	Does the variation in the case definitions by the Member States effect the fulfilment of surveillance objectives?	🗌 No	🗌 Yes	Explain how		
<i>Data quality</i> Annex 3, 5.5	Does the hub check the quality of data before accepting it to the DSN database?	🗌 Yes	🗌 No	Explain how		
Annex 4, 3.2 Annex 5, 3.6	Do the national contact points check the quality of data before reporting to the hub?	Yes, completely	☐ Yes, partially ☐ No	Describe and assess the results.		
Annex 4, 3.3 Annex 5, 3.7	Do the contact points receive feedback on data quality?	Yes, regularly	Yes, sometimes	Describe and assess the results.		
<i>Representativeness</i> Review	How many EU and EFTA countries participate in the DSN by diseases/health issues?	All EU countries All EFTA countries	/ /	Liechtenstein, Norway a only first three of these	four countries; Iceland, and Switzerland. EEA includes countries (not Switzerland). countries are mentioned here.	
Annex 4, 2.4 Review	Did all participating Member States submit the data requested for the evaluation?	☐ Yes	□ No	Compare the list of part corresponding replies fi contact points. If No, explain why not	ticipating countries and rom the national epidemiology	
Annex 5, 2.2	Has the operation increased the coverage of strains/samples of microbe(s) submitted to the reference laboratory?	☐ Yes ☐ Not relevant	☐ No ☐ Don't know			

6. TECHNICAL PE	RFORMANCE	DSN:	Date of evaluation: /				
Source of data	Check questions		Assessment		Remarks		
		Та	rget	Development			
Annex 3, 5.6	Has the hub classified the data according to representativeness at the national level?	□ Yes		🗌 No	Describe how		
<i>Sensitivity</i> & <i>Specificity</i> Annex 3, 5.9	Has the hub taken into account the sensitivity and specificity of case identification at the national level?	☐ Yes		🗌 No	Explain how	Explain how	
Annex 5, 3.4	Have the national reference level laboratories participated in appropriate EQA schemes?		regularly relevant	☐ Yes, occas. ☐ No		e results. Assess the "No" lability of schemes and the ponders.	
Annex 5, 3.5	Have the national laboratories participated in appropriate external quality assurance schemes?		regularly relevant	☐ Yes, occas. ☐ No		e results. Note that the EQA nd identifications are available n bio safety level 2.	
Major strengths:			Major wo	eaknesses:			
Minor strengths:			Minor w	eaknesses:			
The overall impression of the evaluation team on the technical performance			🗌 High		Medium	Low	

7. STRUCTURE A	ND MANAGEMENT	DSN:	Date of evaluation: /		
Source of data	Check questions	Assess	sment	Remarks	
		Target	Development		
<i>Structure</i> Review	Has the DSN a web site?	🗌 Yes	🗌 No		
Review	Does the web site provide enough and appropriate information?	🗌 Yes	🗌 No	Specify in advance wi should be on the web objectives and the str	
Annex 3, 6.1	Does the hub have sufficient and appropriate personnel?	🗌 Yes	🗌 No	Explain why not	
Annex 3, 6.2	Does the hub have sufficient and appropriate technical resources?	☐ Yes	🗌 No	Explain why not	
Annex 3, 6.4	Does the scientific coordinator have sufficient time for scientific surveillance activities?	☐ Yes	🗌 No		e scientific coordinator 35% time available for
<i>Data protection</i> Annex 3, 6.8 Review	Does the data protection fulfil the requirements in the national law of the hosting country for data protection?	Yes	🗌 No	Describe the problem	is, if any.
Annex 3, 6.9	Has the data protection regulations by Member States caused any problems in meeting the data protection regulations in the EU?	□ No	🗌 Yes		s and their importance in ent of objectives of the
Annex 3, 6.10	Is the database accessible to the hub workers only?	☐ Yes	🗌 No		

7. STRUCTURE	AND MANAGEMENT	DSN:	Date of evaluation:		
Source of data	Check questions	Assess	sment	Remarks	
		Target	Development		
Annex 3, 6.11	Does the hub ensure the confidentiality of data when providing it to outside parties on request?	Yes	🗌 No		
Annex 3, 6.12	Has the hub a system for securing continuity of operation in place?	🗌 Yes	□ No	Describe the system	
Annex 3, 6.3 <i>Management</i>	Does the hub have appropriate communication with the team responsible for the surveillance of the disease/health issue at the national level?	☐ Yes	🗌 No		
Annex 4, 2.5 Annex 5, 2.3	Have the national epidemiology and laboratory contact points agreed on who submits the data set to the hub?	☐ Yes	🗌 No	Check the agreemen	t between the replies.
Annex 4, 2.8 Annex 5, 2.5	Assess the workload at national level by number of working days spent with the work related to the DSN	Epi mean , std Lab mean , std	days days		and standard deviation for nd laboratory contact points.
Annex 4, 2.9 Annex 5, 2.6	Assess the subjective workload				ve workload separately for poratory contact points.

7. STRUCTURE A	ND MANAGEMENT	DSN:	Date of evaluation: /		
Source of data	Check questions	Assess	sment	Remarks	
		Target	Development		
Annex 4, 2.10 Annex 5, 2.7 Annex 6, 2.6	How is the management felt by the contact points? => compliance How is the management felt by the State Epidemiologists? => image of the DSN			The opinion of management by the contact points reflects the satisfaction with the management and is closely related to compliance. Describe separately for epidemiology and laboratory contact points. Assess the results. Compare with opinions with the State Epidemiologists.	
Annex 4, 2.11 Annex 5, 2.8 Annex 6, 2.7	What aspects in the operation of the DSN require improvements?				and assess their relative of reaching the surveillance
Annex 3, 6.13	Has the hub recognized how to improve the current way of operation?	🗌 Yes	🗌 No	Describe how	
<i>Decision making</i> Annex 3, 6.5 Review	Has the DSN supervision?	☐ Yes	🗌 No	Describe the supervi	sion (i.e. advisory board)
Annex 3, 6.6 and 6.7	Is the decision making effective and the follow-up of implementation appropriate?	☐ Yes	□ No	the decisions docum	the strategic decisions, are ented and available to the ow well the implementation pred.
Annex 4, 2.7 Annex 5, 2.4	Are the national contact points satisfied with decision making?	☐ Yes, all	/ total	all and separately for	ints. Explain the most

7. STRUCTURE A	ND MANAGEMENT	DSN:	Date of evaluation: /			
Source of data	Check questions		Assess	sment	Remarks	
		Та	rget	Development		
<i>Costs</i> Annex 3, 1.3	Have the funds from the EU been sufficient for fulfilling the objectives of the DSN?	🗌 Yes		🗌 No	Explain why not.	
Annex 3, 1.3	Have the sub-contracting arrangements been satisfactory at national level?	🗌 Yes		□ No	Explain why not.	
Annex 3, 1.3	Have the sub-contracting arrangements been satisfactory at EU level?	🗌 Yes		□ No	Explain why not.	
Major strengths:			Major we	eaknesses:		
Minor strengths:		Minor we	eaknesses:			
The overall impression of the evaluation team on the performance for the structure and management		🗌 High		Medium	Low	

This interview is targeted to the project management team (the hub). Any relevant documentation should be available at the time of interview, and may have been requested by the evaluation team in advance.					
Date of interview:	/	DSN:			
Scientific coordinator:					
Project leader(s):					

1.1	Please, describe which of the listed objectives (from the grant agreeme and how? (<i>The objectives will be listed in advance by the evaluation te</i>	
1.2	How would you rate the performance of the DSN in the following generic international surveillance objectives? Note that not all objectives are relevant for the DSN	Rate the performance 1 = Low, 5 = High, NR = not relevant
	ecord trends of international importance in the occurrence of disease or in characteristics of cases	
are a	scertain in a timely way cases of public importance, particularly those who an immediate danger to contacts, in order to permit diagnosis, treatment, management of contacts, especially when these may be in other countries	
	etect international epidemics or outbreaks, and report national epidemics or reaks of international potential	
have	upport the evaluation of primary and secondary preventive measures that potential international implications (e.g. population screening or recall of a aminated foodstuff)	
	ontribute to estimates of the relative magnitude of morbidity and mortality to an infection (disease burden) between different countries	
	onitor the effects of international differences in clinical practice (tertiary ention), including the use of diagnostic tests and treatment regimes	
g) Fa	acilitate research in support of prevention or control	
1.3	Please, describe major obstacles in achieving the objectives or deliver described in the grant agreement?	ables of the DSN, as
1.4	How does the hub intend to overcome the obstacles?	

1 (6)

2. 4	Alerts and collaboration		
2.1	How many times has the hul initiatives from focal points		to national level based on alerts from the data or ountries?
	times	Not relevant	please, continue with Question 2.3
2.2	What have been the outcom	e(s) of these inqu	liries?
2.3	Has the core function of the	DSN provided ex	pertise for international outbreak investigations?
	☐ Yes	🗌 No	Not relevant
	If Yes, please specify for w	hich diseases and	d how:
	If No, what are the reasons:		
2.4	How many times have you in threats?	nformed the natio	onal contact points about potential acute health
	times	Not relevant	
2.5			rocedures for public health or infection control the results of the surveillance? (2003/542/EC)
	☐ Yes	🗌 No	Not relevant
	If Yes, please specify the do	ocumented action	15:
	lf No or Not relevant, what a	are the reasons:	
2.6	Has the DSN had any co-ope If Yes, please, specify	eration with the fo	bllowing parties:
Proje	ects funded by DG RESEARCH	🗌 No	☐ Yes;
Othe	r research groups of the topic(s)) 🗌 No	☐ Yes;
WHC)	🗌 No	☐ Yes;
	r surveillance projects n EU and non-EU projects)	🗌 No	☐ Yes;
Othe	r co-operation activities	🗌 No	☐ Yes;

2 (6)

3.	Surveillance reports and other outputs from the preceding 3 years
3.1	What kind of reports has the DSN produced?
3.2	What is/are the target group(s) for the produced reports?
3.3	How are the reports made available?
3.4	What is the anticipated reporting time interval for the <u>surveillance</u> reports?
	(number) (time unit) The reporting time is not specified
3.5	What have been the main difficulties or obstacles in interpreting the results of the surveillance?
3.6	In case the DSN has <u>not</u> produced a scientific surveillance report on <i>disease(s)/health issues,</i> please, explain why not:

4.	4. Development of the national surveillance	e systems <u>during the preceding 3 years</u>					
4.1	4.1 How have the national data qualities of report	How have the national data qualities of reporting to the hub improved in time?					
4.2	4.2 How many Member States have improved thei agreed data set?	r reporting towards completeness of minimum					
	/ Member States	Don't know					
4.3	4.3 How has the hub supported the development manner?	of the national surveillance systems in a concrete					

5. T	echnical performance during the preceding 3 years
5.1	How does the hub monitor and report the delays in reporting from the national level to the hub by participating Member States?
5.2	Has the timeliness of data inflow from the national level improved and how appropriate is it at present, relative to its importance for the surveillance objectives of the DSN?
5.3	What are the major obstacles in improving the timeliness of data flow from national level to the hub if any?
5.4	Has the timeliness of surveillance reporting improved and how appropriate is it at present, relative to its importance for the surveillance objectives of the DSN?
5.5	What data checks has the hub employed before accepting the reported data to the DSN database as validated?
5.6	How has the DSN addressed the issue of representativeness of the data at the national level?
5.7	How compatible is/are the case definition(s) of the DSN with the EU case definition(s)?
5.8	How does the variation in the case definitions used in the national surveillance systems of the Member States affect the fulfilment of the objectives of the DSN?
5.9	How is the DSN addressing the sensitivity and the specificity?
5.10	How has the DSN addressed the issue of comparability of data between participating EU countries, if this is relevant to its specific surveillance objectives?

6. S	Structure and management of the DSN <u>during the p</u>	receding 3 years		
6.1	What kind of obstacles due to available personnel resources have there been for meeting the surveillance objectives of the DSN if any?			
6.2	Have there been any obstacles set by technical resources, for meeting the surveillance objectives?	other than shortage of personnel,		
6.3	How closely have you been working with the team responsion disease/health issue at the national level in the country hos			
6.4	What approximate proportion of your time as a scientific co	ordinator has been spent on		
	Financial administrative issues:	%		
	Non-financial administrative issues:	%		
	Surveillance/Scientific activities:	%		
6.5	How has the supervision of the DSN been organized and do	ocumented?		
6.6	Who has made the strategic decisions in the DSN?			
6.7	How has the DSN monitored the implementation of the deci	sions?		
6.8	How has the data protection been organized in the DSN?			
6.9	Have there been any problems in meeting the data protection individual participating Member States?	on regulations in the EU and in the		
6.10	Which parties have had access to the database(s)?			
6.11	What processes has the DSN had in place to reply to reque	sts of data?		

6.12 How is the continuity of the operation secured in the temporary absence of scientific coordinator?

6.13 How would you improve the current way of operation?

Thank you very much for the interview

Please, use the space below for any comments you would like to add:

This questionnaire is targeted to the **national epidemiology** contact point of the (DSN). Please, fill out the questionnaire taking into consideration **the preceding 3 years** of activity of the surveillance network. If you are not able to answer some of the questions, please, complete the information from a person with appropriate knowledge, if possible. All responses are analysed confidentially. They are invaluable for the evaluation of the DSN. The term *disease/health issue* depicts those issues that are covered by the DSN under EU-wide surveillance.

Date	Date of filling out the questionnaire: / DSN:				
Name: Country:			Country:		
1.	Background in	formation			
1.1	When did you	start as a national conta	act point in the DSN?		
	Year:				
1.2	who has nom	nated you to act as a na	tional contact point in th	ie DSN?	
1.3	Do you work a	t a national public healt	h institute?		
	🗌 Yes	🗌 No	🗌 Don't know		
		lf No, please s	pecify where do you wor	k at:	
2. (2. Operation of the DSN during the preceding 3 years				
2.1	Has the operation of the DSN led to any immediate public health actions (e.g. outbreak/cluster investigations, control procedures) for <i>disease(s)/health issu</i> es in your country?				
	🗌 Yes	🗌 No	🗌 Don't know	Not relevant	
	lf Yes, please	specify the actions:			
2.2	•		y improvements in publi) for <i>disease(s)/health is</i>	ic health prevention and control <i>sues</i> in your country?	
	🗌 Yes	🗌 No	🗌 Don't know	Not relevant	
	lf Yes, please	specify the improvement	nts:		
2.3	What other be	nofite have you and the	national survoillance sve	stems acquired from participating	
2.5	in the operatio		national surveinance sys	stems acquired nom participating	

2.4	Does your country submit data to the DSN?				
	🗌 Yes	🗌 No			
		If No, what is/	are the main reasons for not submit	ting data to the hub?	
2.5	Have you agreed with the national laboratory contact point in your country on who submits regularly the data set from your country to the hub?				
	🗌 Yes	🗌 No	Not relevant		
	lf Yes, who s	submits the data set:	:		
2.6	generic inter	ou rate the performa national surveillance all objectives are releva		Rate the performance 1 = Low, 5 = High, NR = not relevant	
		nternational importance	ce in the occurrence of disease or in		
are a	n immediate da	nger to contacts, in or	c importance, particularly those who rder to permit diagnosis, treatment, when these may be in other countries		
	etect internation reaks of internat		eaks, and report national epidemics or		
have		ational implications (e	econdary preventive measures that .g. population screening or recall of a		
			nagnitude of morbidity and mortality een different countries		
			ences in clinical practice (tertiary c tests and treatment regimes		
g) Fa	cilitate research	n in support of prevent	tion or control		
2.7	Have you bee	en satisfied with the	decision making in the DSN?	1	
	🗌 Yes	🗌 No	No opinion		
		lf No, please e	explain why not:		
2.8	How many w	orking days <u>per year</u>	do you approximately spend with t	ne work related to the DSN?	
	About	days			

2.9	How much time have you spent in collecting, managing and validating the data for the DSN?			a for the DSN?	
	Little	Moderate	Much	Very much	Not relevant
2.10	How would you asse	ess the quality of m	anagement of the D	SN?	
	Poor	🗌 Fair		Good	No opinion
2.11	Which aspects in the	e operation of the D	OSN would require in	mprovements?	
3. D	Development of the r	national surveilla	nce system(s) <u>dur</u>	ing the preceding	<u>3 years</u>
3.1	Has the operation of your country?	the DSN led to any	/ improvements in c	lisease(s)/health iss	ues surveillance in
	☐ Yes	🗌 No	🗌 Don't kno	w 🗌 Not	relevant
	If Yes, please specif	fy the improvemen	ts:		
3.2	Do you check the int	ernal consistency	of data before repo	rting to the hub?	
	Yes, completely	🗌 Yes, partially	🗌 No		
3.3	Do you get feedback	on data quality fro	om the hub?		
	Yes, regularly	Yes, sometim	nes 🗌 No	□ Not	relevant
3.4	What are the reasons for possible variation in annual incidences between the data of your country in the DSN database and the published national official data, if any?				
3.5	How compatible is/a DSN?	re the case definiti	on(s) at national lev	el with the case def	inition(s) of the
3.6	Have the case definit definition(s) during t	. ,	-	wards compatibility	with the EU case
	🗌 Yes	🗌 No	🗌 Don't know	w 🗌 Not	relevant
4. lı	nformation dissemir	nation by the DSN	I <u>during the prece</u>	ding 3 years	
4.1	Does the DSN provid issues than is regula				ut disease(s)/health
	🗌 Yes	🗌 No	🗌 Don't kno	w 🗌 Not	relevant

4.2	Have you used any protocols, guidelines or procedures produced by the DSN?			
	🗌 Yes	🗌 No	Not relevant (no documen	ts produced)
	If Yes, please specify:			
4.3	Have you used the information provided in the scientific surveillance report of the DSN, e.g. in your own regular national or international reporting?			ort of the DSN, e.g. in
	Yes	🗌 No	Not relevant (no scientific	surveillance report)
	If Yes, please specify:			
4.4	How useful from your	point of view has been	the information produced by	/ the DSN?
	Not very useful	Useful	Very useful	No opinion
THANK YOU VERY MUCH FOR YOUR REPLY				

Please, feel free to give any comments:	

Annex 5: Questionnaire for the national laboratory contact point

This questionnaire is targeted to the **national laboratory** contact point of the (DSN). Please, fill out the questionnaire considering **the preceding 3 years** of activity of the surveillance network. If you are not able to answer to some of the questions, please, check the reply from a person with appropriate knowledge if possible. All replies are analysed confidentially and they are invaluable for the evaluation of the DSN. The term *microbe(s)* refer to those pathogens that are under EU-wide surveillance by the DSN.

Date	ate of filling out the questionnaire: / DSN:				
Name: Country:			Country:		
1. E	Background info	rmation			
1.1	When did you st	art as a national conta	act point in the DSN?		
	Year:				
1.2	Who has nominated you to act as a national contact point in the DSN?				
1.3	Do you represent a national reference level laboratory for the microbe causing <i>disease(s)</i> under surveillance by the DSN?				
	🗌 Yes	🗌 No			
		lf No, please s	pecify where do you wor	k at:	
2. (2. Operation of the DSN during the preceding 3 years				
2.1	What benefits have you and the national laboratory network acquired from participating in the operation of the DSN?				
2.2		n of the DSN increase reference laboratory		of strains/samples of <i>microbe(s</i>)	
	🗌 Yes	🗌 No	Don't know	☐ Not relevant	
2.3		l with the national epi a set from your count		in your country on who submits	
	🗌 Yes	🗌 No			
	lf Yes, who subi	mits the data set:			
2.4	Have you been s	atisfied with the decis	sion making in the DSN?		
	🗌 Yes	🗌 No			
		lf No, please e	xplain why not:		
2.5	How many worki	ng days <u>per year</u> do y	/ou approximately spend	I with the work related to the DSN?	
	About	days			

Annex 5: Questionnaire for the national laboratory contact point

2	(2)
2	(S)

2.6	How much time you h	ave spent in collecting	g, managing an	d validating the c	lata for the DSN?
	Little	Moderate	Much	Very much	Not relevant
2.7	How would you asses	ss the quality of manag	jement of the D	SN?	
	Poor	🗌 Fair		Good	No opinion
2.8	Which aspects in the	operation of the DSN v	vould require i	mprovements?	
3. C	Development of the n	ational laboratory ne	twork <u>during</u>	the preceding 3	<u>years</u>
3.1	Has the operation of t including the reference	the DSN led to any imp ce laboratory?	rovements in c	competence of na	tional laboratories
	🗌 Yes	🗌 No	🗌 Don't knor	w 🗌 N	ot relevant
	If Yes, please specify	the improvements:			
3.2	Has the operation of t	the DSN led to any imp	rovomonte in r	rotocol(c) or pro	onduros for taking
5.2	Has the operation of the DSN led to any improvements in protocol(s) or procedures for taking specimens to investigate any of the <i>microbe(s)</i> under surveillance of the DSN?				
	Yes	🗌 No	🗌 Don't knor	w 🗌 N	ot relevant
	If Yes, please specify	<i>the improvements:</i>			
3.3	Has the operation of the DSN led to any improvements in use of standardised method(s) for isolation and identification of any of the <i>microbe(s)</i> under surveillance of the DSN?				
	Yes	🗌 No	Don't knor	w 🗌 N	ot relevant
	If Yes, please specify	the improvements:			
3.4		at you represent partic nal reference laboratory gy and molecular microl	may participate	in EQA schemes	for advanced
	🗌 No	Yes, occasionally	🗌 Yes, regu	larly 🗌 N	ot relevant
	lf No, please explain	why not:			
3.5		oratories participated i nal laboratories may par			
	🗌 No	Yes, occasionally	🗌 Yes, regu	larly	Not relevant
3.6	Do you check the inte	ernal consistency of m	icrobiological d	lata before repor	ting to the hub?
	Yes, completely	Yes, partially	🗌 No		

Annex 5: Questionnaire for the national laboratory contact point

3.7	Do you get feedback o reporting?	on data quality from the	hub or the national contac	ct point responsible for
	Yes, regularly	Yes, sometimes	🗌 No	Not relevant
3.8			n annual incidences betwee ed national official data, if a	
4. Ir	nformation dissemina	ation by the DSN <u>duri</u>	ng the preceding 3 years	2
4.1			ailed analysis or information in the second structure in the second structure in the second structure in the second structure is a second structure is a second structure in the second structure in the second structure is a second structure in the second structure is a second structure in the second structure in the second structure in the second structure is a second structure in the second st	
	🗌 Yes	🗌 No	Don't know	☐ Not relevant
4.2	Have you used any pr	otocols, guidelines or p	procedures produced by th	e DSN?
	☐ Yes	🗌 No	🗌 Not relevant (no docume	ents produced)
	If Yes, please specify	:		
4.3		ormation provided in th onal or international rep	ne scientific surveillance re porting?	port of the DSN, e.g. in
	🗌 Yes	🗌 No	Not relevant (no scientif	ic surveillance report)
	If Yes, please specify	:		
4.4	How useful from your	point of view has been	the information produced	by the DSN?
	Not very useful	Useful	Very useful	🗌 No opinion

THANK YOU VERY MUCH FOR YOUR REPLY

Please, feel free to give any comments:	

Annex 6: Questionnaire for the key national stakeholder

This questionnaire is targeted to the **key national stakeholder** of the (DSN). Please, fill out the questionnaire taking into consideration **the preceding 3 years** of activity of the surveillance network. All responses are analysed confidentially. They are invaluable for the evaluation of the DSN. The term *disease(s)/health issues* depicts those issues that are under EU-wide surveillance by the DSN.

Date of filling out the questionnaire: /	Position:
Name:	Country:

1	1 Background information								
1.1	Please, indicate whether you have or have had the following roles in the DSN?								
		Code	2 = Yes, I	am at present have been in the past have never had the role					
a)	Project leader								
b)	Project co-ordinator								
c)	Member of the advisory/steering committee								
d)	National contact point								
e)	Other, please specify:								
2 . O	peration of the DSN <u>during the preceding</u>	<u>3 years</u>							
2.1	Has the operation of the DSN led to any immediate public health actions (e.g. outbreak/cluster investigations, control procedures etc.) for <i>disease(s)/health issues</i> in your country?								
	Yes No	🗌 Don't k	now	Not relevant					
2.2	Has the operation of the DSN led to any improvements in public health prevention and control policies (i.e. vaccination programmes) for <i>disease(s)/health issues</i> in your country?								
	Yes No	🗌 Don't k	know	Not relevant					
2.3	Has the operation of the DSN led to any improvements in <i>disease(s)/health issues</i> surveillance in your country?								
	Yes No	🗌 Don't k	now	Not relevant					
2.4	What benefits has the operation of the DSN provided <u>you</u> in your work?								
2.5	How would you rate the performance of the DSN in the following generic international surveillance objectives? Note that not all objectives are relevant for the DSN			Rate the performance 1 = Low, 5 = High, NR = not relevant 9 = Don't know					
a)	Record trends of international importance in the or in the characteristics of cases	occurrence of o	disease						

Annex 6: Questionnaire for the key national stakeholder

2 (3)

b)	Ascertain in a timely way cases of public importance, particularly those who are an immediate danger to contacts, in order to permit diagnosis, treatment, and management of contacts, especially when these may be in other countries						
C)	Detect international epidemics or outbreaks, and report national epidemics or outbreaks of international potential						
d)	Support the evaluation of primary and secondary preventive measures that have potential international implications (e.g. population screening or recall of a contaminated foodstuff)						
e)	Contribute to estimates of the relative magnitude of morbidity and mortality due to an infection (disease burden) between different countries						
f)	Monitor the effects of international differences in clinical practice (tertiary prevention), including the use of diagnostic tests and treatment regimes						
g)	g) Facilitate research in support of prevention or control						
2.6	How would you assess the quality of management of the DSN?						
	Low Fair Satisfactory Good	No opinion					
2.7	Which aspects in the operation of the DSN would require improvemen	ts?					
2 Information discomination by the DCNI during the proceeding 2 was as							
3. Information dissemination by the DSN <u>during the preceding 3 years</u>							
3.1	Which of the outputs below, based on data from the DSN, have you us	ed in your work?					
a)	Publication(s) in a bulletin of national surveillance centre						

b)	Scientific publication(s) in Eur	osurveillance						
c)	Scientific publication(s) in ano	ther peer reviewed scie	ntific journal(s)					
d)	Scientific surveillance report o	of the DSN						
e)	Web site of the DSN							
f)	Other, please, specify:							
3.2	How useful from your point of view has been the information produced by the DSN?							
	Not very useful	Useful [Very useful		No opinion			

THANK YOU VERY MUCH FOR YOUR REPLY

Annex 6: Questionnaire for the key national stakeholder

Please, feel free to give any comments:

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