

# **EUROPEAN COMMISSION**

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment Director

Luxembourg, 21 September 2005 D(2005) FS/SB/MCA/es/330

Zsuzsanna Jakab Executive Director of the European Centre for Disease Prevention and Control (ECDC) Solna Stadshus SE-171 86 Solna Sweden

**Subject: Communicable diseases Handover of files** 

Dear Zsuzsanna,

When we transferred in mid-July the administrative and financial files from SANCO/C6 to the ECDC and after you took over the function of authorizing officer, we agreed that assembling and handing over all the scientific and technical work from SANCO/C3 communicable diseases and bioterrorism activities would take more time during the summer months. As a result of many contacts between our collaborators, I am glad to share with you all files and documents related to the areas of work of direct or indirect interest to the ECDC, that Unit SANCO C/3 "Health Threats" has been pursuing so far.

We have compiled all relevant documents in a compendium that we will make available on a DVD, together with the earlier handover files from Unit SANCO/C/6 in July. With this DVD, the ECDC staff and bodies, as well as our own staff and committees, will be able to share the same initial reference material in the areas of communicable diseases and bioterrorism. In this compendium, we left out individual contact details because of confidentiality, security and constant modifications. The latest information concerning such individual contact points will be communicated directly to the ECDC designated contact person. As you may want to consider distributing this DVD to your Management Board and Advisory Forum, we thought of producing before end of September some 150 copies for the ECDC, and some 150 copies for our own needs.

You will find in Annex 1 an overview of past and ongoing activities in the field of communicable diseases and bioterrorism. All documents are now accessible to you through the CIRCA website and/or on the EUROPA public web sites stated addresses.

Annex 2 describes concisely DG SANCO/C/3's work on developing EU capabilities to respond to public health threats posed by bioterrorism since 2001.

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Annex 3 constitutes a jointly agreed description, between our respective services over summer, to lay out the basis for sharing future work between SANCO/C3 and ECDC. This future collaboration will have to be adjusted to annual priorities established by the Commission for health policy and by the ECDC Management Board for your annual work programme, taking into account the growing capacities of the ECDC.

Annex 4 gives an indicative list of tasks of common interest, to be conducted over the years by the ECDC, or the Commission services, or shared between the two.

This complex documentation should provide the ECDC with an adequate overview of the work done so far by DG/SANCO. Some of the tasks are already completed, whereas other tasks are still on-going. I trust that, through regular contacts, proper consultation and regular attendance to our respective meetings, we can avoid duplication and overlap.

Turning now to our highest priority in the coming months, influenza pandemics, we both agreed during our recent contacts that cooperation and sharing out work is essential. The Commission will, in consultation with you, set out more precisely its needs for assistance from the ECDC. In anticipation of a series of meetings with Member States experts in the coming weeks, to which the ECDC has also been invited, we should be able to respond to urgent requests from the Commissioner, from Health Ministers and Parliament.

On the basis of our earlier discussions, I would suggest that the following issues could become our first priorities. If you agree, taking into account the human resources available, the ECDC would provide technical and scientific assistance as well as opinions where relevant on topics such as:

- Conducting risk assessment of the actual human influenza pandemic situation and state of preparedness at EU and national level.
- Analysing in real-time and assessing the risk for humans of latest developments on AI and pandemic flu (including a weekly analysis report to Commission).
- Providing relevant and up-to-date scientific and background information and guidance on influenza to the public and relevant health professionals.
- Conducting risk assessment and providing guidance for humans in direct contact to birds suspected to be positive for AI which might infect humans (e.g., H5N1)
- Sharing our reviews and analysis of National Preparedness Plans on Influenza, taking into account the EU- and the WHO Influenza plans.
- The quick identification of pandemic strains through surveillance and networking of National Reference Laboratories, benefiting from the EISS project.
- Early notification of cases and outbreak assistance and timely advice for effective outbreak management.
- Update the current status on national stockpiling of vaccines and anti-viral drugs interventions and design a plan to protect first line operators (also EU level).

In order to give visibility to such actions, the pandemic areas of work could be summarised by your services in a weekly tabular form, to be shared with Commissioner Kyprianou, DG SANCO and during relevant Member States experts meetings.

# Best Regards,

#### Fernand Sauer

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# Enclosures:

<u>Annex 1:</u> Overview of activities of DG SANCO C3 in the field of communicable

diseases and bioterrorism

<u>Annex 2</u>: EU capabilities to respond to public health threats posed by bioterrorism

Annex 3: Basis for sharing work between DG SANCO C3 and ECDC

Annex 4: Indicative list of tasks to be conducted over the years by Commission

services, ECDC or shared

# ANNEX 1

# Overview of activities of DG SANCO C3 in the field of communicable

# diseases and bioterrorism

# 1. <u>COMMUNITY NETWORK ON THE EPIDEMIOLOGICAL</u> SURVEILLANCE AND CONTROL OF COMMUNICABLE DISEASES

DOCUMENTS CONCERNING THE COMMUNITY NETWORK ARE ALL AVAILABLE ON CIRCA WEBSITE, SEE: http://forum.europa.eu.int/Members/irc/sanco/hsscd/library

# 1.1 Legislation

- Decision 2119/98/EC of the European Parliament and of the Council setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.
- Commission Decision (2000/57/EC) on the early warning and response system for the prevention and control of communicable diseases;
- Commission Decision (2000/96/EC) on the communicable diseases to be progressively covered by the Community network
- Commission Decision (2002/253/EC) laying down case definitions for reporting communicable diseases to the Community network
- Commission Decision (2003/534/EC) amending Decision No 2119/98/EC and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions;
- Commission Decision (2003/542/EC) amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks.

#### 1.2 ESCON

- Meetings (including minutes) 2003, 2004 and 2005
- Nominations and Memberships

  Documents of meetings on CIRCA web site under the date of the meetings

#### 1.3 EWRS

- Meetings (including minutes) 2004 and 2005
   Documents of meetings on CIRCA web site under the date of the meetings
- The standard operating procedures (SOPs).

  All working documents /guidelines are available on the CIRCA web site under the working documents 2003-2005 folder of the Meetings section
- Nominations and Memberships
- EWRS report 2002-2003
- A 24 hour/7 day-a-week on-duty service is established and run by C3 for EWRS and for rapid alerts on biological, chemical and radiation agent attacks and threats

#### 1.4 Regulatory Committee

- Meetings (including minutes) 1999-2003
- List of representatives
- Rules of Procedures of the Network Committee
  All relevant documents of the meetings can be found on the CIRCA web site
  under the date of the meeting

# 2. <u>ANTIMICROBIAL RESISTANCE</u>

- Council recommendation (2002/77/EC) of 15 November 2001 on the prudent use of antimicrobial agents in human medicine
- Reports received from Member States on the implementation of the Council Recommendation 2002/77/EC

# 3. <u>INFLUENZA</u>

Key documents on Influenza Preparedness and Response Planning are available on public health website, see:

http://europe.eu.int/comm/health/ph threats/com/Influenza/keydo influenza en.htm

#### In particular:

- Commission Working Paper on Community Influenza Pandemic Preparedness and Response Planning which is currently under revision
- Upcoming command-post exercise coordinated by the Commission involving all the Member States

# 4. **BIOTERRORISM**

DOCUMENTS CONCERNING BIOTERRORISM ARE AVAILABLE ON CIRCA WEBSITE, SEE:

http://forum.europa.eu.int/Members/irc/sanco/phab/library

#### In particular:

- Communication from the Commission to the Council and the European Parliament on cooperation in the European Union on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security)
- Programme of cooperation on preparedness and response to biological and chemical attacks (Health Security)

# 5. <u>DEDICATED SURVEILLANCE NETWORKS</u>

List of DSN contact points available on CIRCA website, see:

http://forum.europa.eu.int/Members/irc/sanco/hsscd/library?l=/nominations\_membership\_s/dsn\_contact\_points&vm=detailed&sb=Title

# 6. OTHER COMMUNICABLE DISEASE ISSUES

For relevant information on other issues like HIV/AIDS and emerging diseases (SARS, West-Nile Virus, rabies, etc.) we refer to the relevant domains on our public health web site, see:

http://europe.eu.int/comm/health/ph\_threats/com/emerging/emerging\_en.htm and http://europe.eu.int/comm/health/ph threats/com/aids/aids en.htm

# 7. PROJECTS FINANCED BY THE COMMISSION

Project description of projects, including DSNs financed (2003 and 2004) under Public Health Programme, see:

http://europe.eu.int/comm/health/ph\_projects/action2\_en.htm and http://europe.eu.int/comm/health/ph\_threats/com/comm\_diseases\_networks\_en.htm

Project description of relevant projects financed (1995 - 2002) under AIDS & other communicable diseases programme, see: http://europe.eu.int/comm/health/ph projects/comdiseases project en.htm

Geographical overview of projects coordinated from which Member States

Time line of on-going projects, including DSNs indicating when grant agreements with Commission will come to end (see table 1 below)

List of project proposals received under 2005 call for proposals that were accepted and are under negotiation for grant agreement (see table 2 below)

<u>Table 1</u>: Projects co-funded by Commission in area of communicable disease, including DSNs (indicating disease/topic addressed, total budget, and end)

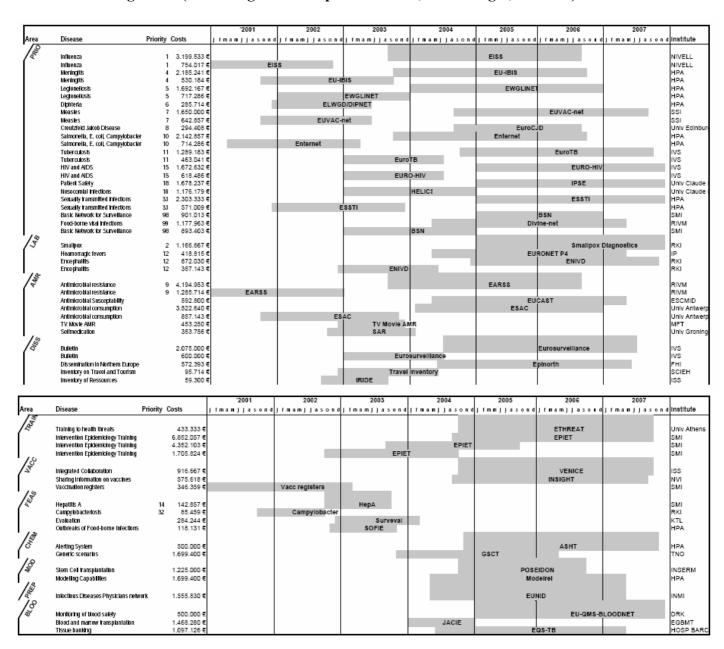


Table 2: List of project proposals received under 2005 call for proposals that were accepted and are under negotiation for grant agreement **Project** Title 2005 projects Recommended Acronym Area Officer Budget Violetta **ETIDE** European Training for Infectious Capacity 1.055.468,00 Skarzinskie Disease Emergencies Building **Boguslav EpiSouth** Network for Communicable Diseases Capacity 1.724.904,00 Suski Control in Southern Europe and Building Mediterranean Countries 1.119.986,00 Helmut EBug Pack Development and Dissemination of a **AMR** Walerius Antibiotic and Hygiene Education Pack and Website across Europe Frank **BURDEN** Burden of Disease and Resistance in **AMR** 1.140.000,00 Van Loock **European Nations** Vaccines **EPIVAC** Europe-wide pandemic influenza 540.000,000 coverage: good epidemic vaccination practice by establishing national stakeholder networks Sol FLU-Combating FLU in a Combined 3.749.777,00 Vaccines Action between Industry and the Wallyn **SECURE** Public Health Sector in order to SECURE Adequate and Fast Interventions in Europe **ABS** Implementing Antibiotic Strategies **AMR** 803.736,000 Stef Bronzwaer International (ABS) for Appropriate Use of Antibiotics in Hospitals in Member States of the European Union Diphtheria Surveillance Marie-**DIPNET** European Surveillance 1.336.274,00 Christine Network Avargues Germain **SHIPSAN** Assessing the Usefulness of a EU Surveillance 359.875,000 Thinus Programme Sanitation Coordinated Action for the Control

of Communicable Diseases in Cruise

Vaccine Safety – Attitudes, Training

900.000.00 €

Vaccines

Ships and Ferries

and Communication

VACSATC

Paolo Guglielmetti

# ANNEX 2

# EU capabilities to respond to public health threats posed by

# bioterrorism

# **Legal Context**

- Council/EP Decision 2119/98/EC establishes a network for the epidemiological surveillance and control of communicable diseases.
- Commission Decision of 22 December sets up and Early Warning and Response System for the control of communicable diseases (EWRS).
- Health Council December 2001 agrees with Commission to setting up a Health Security Committee and its programme of activities.
- A communication (COM (2003) 320) on progress with the implementation of the health security programme was published on 2 June 2003;
- Case definitions for bioterror agents were laid down in Commission Decision 2003/534/EC of 17 July 2003.

# **Rapid Alert System**

A secure 24 hour/7 day-a-week rapid alert system for biological, chemical and radiation agent attacks and threats (RAS-BICHAT) has been set up and is operational since June 2002. It is linked to and complements (as regards chemical agent releases and biological agent releases without manifestation of disease) the early warning and response system for the prevention and control of communicable diseases. It hooks up with alert systems on risks related to food and feed safety, animal and plant health and with the ECURIE system for releases of radioactive effluents from nuclear installations, the civil protection Monitoring and Information Centre, as well as the Global Health Security Initiative alert and risk communication system (between the G7 and Mexican Health Ministries and the Commission/DG SANCO)

#### **International co-operation: Global Health Security Action Initiative:**

This initiative was agreed by the G7 and Mexican Health Ministers and Commissioner Byrne in Ottawa on 7 November 2001 and has similar goals to those of the EU cooperation (collaboration on smallpox emergency plans and training, laboratory detection techniques, risk management and communication, chemical incident preparedness, patient isolation techniques). The WHO is fully associated in these activities. The Commission has been tasked with the establishment of a co-operation platform on biosafety research. The next meeting of Ministers and the Commissioner will take place in autumn 2005 in Rome.

#### **Health Security achievements**

- A tool to evaluate and classify the severity of an incident was developed;
- A matrix model has been developed and used on a restricted basis for prioritising bioterror agents and actions on bioterrorism;
- Ten clinical diagnosis and case management guidelines have been published;
- A training course and materials on forensic epidemiology have been prepared together with Europol for training Member States' trainers from law enforcement and field epidemiologist services; one train-the-trainers course has been held and another is to be conducted with the new Member States;
- Laboratory assistance: a EU network for laboratory under the HSC was formed, a network of high security (P4) laboratories has been established and a ring test and a quality assurance project are being prepared.
- Co-ordination and evaluation of emergency plans: Exchanges on smallpox emergency plans have been organised with Member States' experts and smallpox. A table has been compiled comparing corresponding measures and alert levels. A similar effort was carried out jointly with the WHO-European Office on pandemic influenza plans;
- Assistance was provided to three Member States for contingency plans for major sporting events;
- Modelling of outbreaks and data for simulations: Member States' experts and experts from the Commission are working together to develop a generic model which can be subsequently adapted to include specific conditions in Member States and also set up a database from which models can draw;
- Monitoring of Web-based information to provide advance warning of suspicious circumstances or outbreaks: A system (MediSys) has been set up with links to existing systems under the External Relations Directorate-General of the Commission, the Joint Research Centre, the Canada Global Public Health Information Network and the US' CDC and Department of Health and Human Services;
- A "Health Security Bulletin" is distributed regularly to the authorities of the Member States and the partners of the Global Health Security Initiative following a screening procedure using principally the MedISys system;
- Dilution of existing smallpox vaccines and Vaccinia immuno-globulin development and production: A study has been completed on the first and information from the industry has been collected for the second which is a key biological substance for smallpox immunisation, the lack of which is a drawback for mass vaccination plans; the development of vaccines for other agents and vaccination strategies are now being pursued;
- Chemical event scenarios and clinical toxicology guidelines: An EU group has been formed, a project on chemical threat agents and scenarios has been undertaken and advice to EU citizens on protection from chemical agent releases has been published;
- An incident investigation and environmental sampling group has been formed to develop EU-wide protocols and share good practice and know-how and a workshop with a field exercise is being planned to arrive at compatible protocols and EU-wide guidelines.

# Further actions for the implementation of the Health Security Programme

A Generic Public Health Preparedness Planning document was drafted with support of the Working Group of Planners, and was endorsed by the Health Security Committee in April 2005. It includes a planning process, checklists and verification proposal for Member States and an identification of other fields of competences in the Member States and the Commission involving public health. All relevant services (RTD, REGIO, JRC, ENV, ENTR, GOPA) received the document and were invited to the Health Security meetings. A general presentation was given at the Interservice Group on Health in May. A Communication to Council and the European Parliament on Prepardness

Planning is due for interservice consultation in September 2005.

Scenario building and training exercises A priority is to intensify work on emergency planning and to promote modelling, to permit the refinement and strengthening of emergency and strategic plans for threats and attacks.

Exercises internationally (Global Health Security Action Group, Exercise Global Mercury) and stock-taking at EU-level showed that the process of developing emergency plans is not yet complete, with some Member States more advanced than others. Emergency plans, tested with exercises ensuring smooth interdisciplinary working, would provide confidence in the capacity to mount a proportional multi-sector response. Two exercises are planned involving all the Member States and coordinated by the Commission, the first on pandemic influenza (in Autumn), the second on a smallpox emergency.

- Directory of Experts for health sector assistance: Knowledge about bio-terror agents and corresponding diseases and their clinical and epidemiological management and laboratory analysis is limited. Identifying experts in the EU and listing them in a Directory to be shared by Member States authorities will contribute to mutual assistance. A Directory of experts has already been set up, but more information from States on resources available and willing to participate is needed.
- Laboratory co-operation: A project 2004 on improvement of Smallpox Diagnostics Tests together with Russia has been set up. The Robert Koch Institute in Berlin agreed to run the project with the Swedish Institute of Public Health in Stockholm. An Anthrax Wet lab exercise will be hosted by Health Protection Agency (UK) and is due to start early 2006.
- A Workshop on Environmental Sampling of Biological Warfare in May 2006 (Denmark) will be conducted in the form of lectures, exercises and discussions based on the Standard Operational Procedures (SOP) used by the Sampling Teams. Results will serve as starting point for the development of a draft "Best Practice" for Sampling Teams in the EU Member States (MS).
- Enhancement of surveillance capacities through the coordination action of the new European Centre for Disease Prevention and Control (ECDC) which started in Stockholm in May 2005..

# Vaccination for high-threat biological agents

- Information has been obtained and shared, on a restricted basis, on stocks of bioagent vaccines and antibiotics in Member States and general information has been agreed to be collected on medical resources for disaster medicine purposes on the basis of questions formulated by the Health and Consumer Protection Directorate-General and included in a inventory questionnaire sent by DG Environment Civil Protection to the Member States. Under the Council Decision of 2001 setting up the Civil Protection Mechanism (for channelling assistance requests between the Member States), it is required to assemble from the Member States general information on medical resources for emergencies including vaccines, sera, antidotes etc.
- Guidelines have been issued by the EMEA following a mandate and approval by the Commission on the use of medicines against potential pathogens and guidance has been provided on the development of vaccinia virus- based vaccines against smallpox;
- Gaps remain and need to be gradually filled in, with research and development of vaccines still needed on many high risk level viruses (i.e. West-Nile virus).

# ANNEX 3

# Basis for sharing work between DG SANCO C3 (Health Threat Unit) and the European Centre for Disease Prevention and Control (ECDC)

With the European Centre for Disease Prevention and Control (ECDC) now operational, the purpose of this document is to clarify the distribution of work between the Commission service dealing with health threats (SANCO C3) and the ECDC.

This will further promote smooth collaboration between the Commission, the Member States (MS) and the ECDC in the area of public health, and avoid duplication of activities between the relevant Commission services and the agency.

# 1. The legal basis to EU actions

# 1.1.1. Article 152 of the Treaty establishing the European Community

The legal basis for community activities in the area of public health is stipulated in the Article 152 of the Treaty establishing the European Community; "Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education."

# 1.1.2. Decision 2119/98/EC of the European Parliament and of the Council and implementing decisions by Commission

Based on Article 152, the Commission has been building capacity and initiated collaboration with the MS in the area of control of communicable diseases. The community actions in this field have been defined in:

 Decision 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.

Through the procedures in Decision 2119/98, the following implementing decisions have been adopted:

- Commission Decision (2000/57/EC) 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;
- Commission Decision (2000/96/EC) 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;
- Commission Decision (2002/253/EC) 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;
- Commission Decision (2003/534/EC) 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;
- Commission Decision (2003/542/EC) of 17 July 2003 amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks.

# 1.1.3. Regulation establishing the European Centre for Disease Prevention and Control (ECDC)

The ECDC was established in Solna, Sweden, and became operational on May 20, 2005. The missions and tasks of ECDC are defined in Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control.

# 2. Cooperation between the Commission, Member States and the ECDC

#### 2.1.1. Commission

Decision 2119/98/EC (Article 10 and Article 14)

The Commission shall:

- foster cooperation with non-member countries and international organisations competent in the field of public health, in particular the World Health Organisation;
- The Commission shall submit regular reports evaluating the operation of the Community network to the European Parliament and the Council, in particular to identify those elements of the Community network which should be improved or adapted.

Regulation 851/2004/EC (Article 3, paragraphs 3; Article 14):

The Commission shall:

- cooperate with the Centre and the Member States to promote effective coherence between their respective activities:
- through their representatives in the ECDC Management Board, adopt the internal Rules of Procedures of the ECDC, adopt its Work Programme, and ensure that the Centre carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation including on the basis of regular independent and external evaluations to be carried out every five years.

#### 2.1.2. ECDC

Regulation 851/2004/EC (Article 3, paragraphs 1 and 3):

The Centre shall:

- In pursuing its mission take full account of the responsibilities of the Member States, the Commission and other Community agencies, and of the responsibilities of international organisations active within the field of public health, in order to ensure comprehensiveness, coherence and complementarity of action;
- cooperate with the Commission and the Member States to promote effective coherence between their respective activities.

#### 2.1.3. Member States

Decision 2119/98/EC (Article 10)

#### Member States shall:

• foster cooperation with non-member countries and international organisations competent in the field of public health, in particular the World Health Organisation;

Regulation 851/2004/EC (Article 3, paragraph 3; Article 14; Article 18):

#### Member States shall:

- cooperate with the Centre and the Commission to promote effective coherence between their respective activities;
- through their representatives in the ECDC Management Board, adopt the internal Rules of Procedures of the ECDC, adopt its Work Programme and ensure that the Centre carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation including on the basis of regular independent and external evaluations to be carried out every five years.
- through their representatives in the ECDC Advisory Forum, ensure close cooperation between the Centre and the competent bodies in the Member States in particular on the following items:
  - o coherence of the Centre's scientific studies with Member States;
  - o in those circumstances where the Centre and a national body cooperate;
  - o the promoting, starting up and supervising of the European networks within the fields of the Centre's mission;
  - o where the Centre or a Member State identifies an emerging public health threat;
  - o the setting up of scientific panels by the Centre;
  - o scientific and public health priorities to be addressed in the work programme.

# 2.1.4. *Summary*

It is the clear intention in the various legislative acts that the Commission, the ECDC, and the Member States shall work in close cooperation with each other, as well as with international organisations, in particular the WHO, in order to ensure comprehensiveness, coherence and complementarity of action.

# 3. Proposing and adopting measures

#### 3.1.1. Commission

Decision 2119/98/EC (Articles 7, 10 and 14)

#### The Commission shall:

- chair the Network Committee for the purposes of implementing Decision 2119/98/EC;
- submit to the Network Committee a draft of the measures to be taken;

- adopt the measures envisaged if they are in accordance with the opinion of the Network Committee;
- if the measures envisaged are not in accordance with the opinion of the Network Committee, or if no opinion is delivered, without delay submit to the Council a proposal relating to the measures to be taken;
- adopt the proposed measures, if within three months of the matter being referred to it the Council has not acted;
- with the help of the Member States, ensure that there is consistency and complementarity between Decision 2119/98 and the relevant Community programmes and initiatives;
- identify those elements of the Community network which should be improved or adapted;
- propose to the European Parliament and the Council what it considers necessary for the amendment or adaptation of this Decision.

#### 3.1.2. Member States

Decision 2119/98/EC (Articles 7 and 10)

Member States shall:

- for the purposes of implementing Decision 2119/98/EC, assist the Commission in the Regulatory Committee;
- in the Regulatory Committee opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter.

# *3.1.3. Summary*

The Commission will maintain its overall supervision and existing legislative powers under Decision 2119/98/EC in order to set technical requirements and procedural obligations, which will have to be implemented and used by all the components of the Community Network. The Commission has thus the key role in proposing and adopting measures within the field. Strict procedures for this are set up in Decision 2119/98/EC.

As there is no formal reference to ECDC in Decision 2119/98/EC there is no formal role for ECDC in this process. However, as an expert agency, the ECDC will have an important role in advising the Commission on scientific and technical issues, supporting the Commission in the development of measures where needed, and to assist the Commission in preparing relevant background material. In this respect the ECDC will be fully associated in the work of the Community Network.

An evaluation of the implementation of Decision 2119/98/EC from a scientific, technical, legislative and administrative perspective shall be carried out, and the role of ECDC in the context of the Community Network will be addressed in this evaluation.

# 4. Risk identification and risk assessment

4.1.1. Commission

Decision 2000/57/EC (Article 3):

The Commission shall:

• on the basis of the reports from the Member States, examine in an annual report the operation of the early warning and response system and, if necessary, propose changes thereto

#### 4.1.2. ECDC

Regulation 851/2004/EC (Article 3, paragraph 1; 5, paragraph 4; Article 8, Paragraphs 1-2, Article 10, Paragraphs 1 and 3):

#### The Centre shall:

- identify and assess emerging threats to human health from communicable diseases;
- establish, in cooperation with the Member States, procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging health threats which may have mental as well as physical health consequences and which could affect the Community;
- support and assist the Commission by operating the early warning and response system (EWRS);
- analyse the content of messages received by it via the EWRS;
- take action to ensure that the early warning and response system is efficiently and effectively linked with other Community alert systems (e.g. animal health, food and feed and civil protection);
- provide information, expertise, advice and risk assessment;
- inform the Commission and Member States as soon as possible about findings which require their immediate attention.

#### 4.1.3. Member States

Decision 2119/98/EC (Article 4a-d)

Member States shall communicate to the Community network:

- information regarding the appearance or resurgence of cases of (listed) communicable diseases in the Member State;
- any relevant information concerning the progression of epidemic situations for which it has responsibility for information collection;
- information on unusual epidemic phenomena or new communicable diseases of unknown origin;
- on new communicable diseases of unknown origin in non-Member States.

Decision 2000/57/EC (Article3, Annex I, Annex II, paragraph 1(3))

#### Member States shall:

- inform the Community network without delay via the early warning and response system on "EWRS events":
  - Outbreaks of communicable diseases extending to more than one Member State of the Community;

- 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;
- 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;
- The appearance or resurgence of a communicable disease or an infectious agent which may require timely, coordinated Community action to contain it;
- assess the information collected without delay to ascertain if an event with a public health threat exists.
- submit to the Commission not later than 31 March an analytical report of the events and
  on the procedures applied within the early warning and response system. In addition, the
  competent authorities in Member States may on a timely basis report on specific events of
  particular significance

Regulation 851/2004/EC (Article 4a and b)

#### Member States shall:

- provide to the Centre in a timely manner available scientific and technical data relevant to its mission;
- communicate to the Centre any messages forwarded to the Community network via the early warning and response system.
- through their representatives in the ECDC Advisory Forum, ensure close cooperation between the Centre and the competent bodies in the Member States on:
  - o in those circumstances where the Centre and a national body cooperate;
  - o where the Centre or a Member State identifies an emerging public health threat.

# 4.1.4. Summary

Identification and assessment of health threats is a key responsibility for the ECDC, in order to support the Commission and the Member States. The Member States have a clear responsibility to provide to the Centre and to the Community network all available relevant information. For these purposes there is a need both for the formal communications between competent authorities regulated in Decisions 2119/98/EC and 2000/57/EC, and more informal communications on other events.

The EWRS will be operated by ECDC, according to Regulation 851/2004/EC, as soon as the necessary technical infrastructure and organisational arrangements for this is in place at the Centre.

# 5. Preparedness planning

#### 5.1.1. Commission

Decision 2119/98/EC (Article 3 f)

The Commission shall:

• Adopt through the procedures laid down in Article 7 of Decision 2119/98/EC:

o guidelines on the protective measures to be taken, in particular at external frontiers of the Member States, notably in emergency situations.

Decision 2000/57/EC (Annex II, paragraph 2.1)

The Commission shall:

 assist in coordinating the precautionary measures in preparing for any possible public health threat.

#### 5.1.2. ECDC

Regulation 851/2004/EC (Article 3, paragraph 2e; Article 5, paragraphs 3,4; Article 8, paragraphs 1-2; Article 9, paragraph 1):

The Centre shall:

- provide scientific and technical expertise to the Member States, the Commission and other Community agencies in the development, regular review and updating of preparedness plans, and also in the development of intervention strategies in the fields within its mission.
- cooperate with the competent bodies recognised by the Member States on preparatory work for technical assistance;
- within the field of its mission exchange information, expertise and best practices;
- by encouraging cooperation between expert and reference laboratories foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health;
- ensure with the Member States the capacity to respond in a coordinated manner.

#### 5.1.3. Member States

Decision 2119/98/EC (Article 7)

Member States shall:

• for the purposes of implementing Decision 2119/98, assist the Commission in the Network Committee.

# *5.1.4. Summary*

Each Member State is responsible for the preparedness planning in their respective countries. ECDC shall in every way support this work by providing scientific and technical support.

On the Community level, there is a shared responsibility for coordination between the Commission and the ECDC, and a close cooperation between the two is therefore necessary. When needed, the Commission will, with the technical and scientific support from the ECDC, adopt guidelines and other protective measures, through the procedures set up in Decision 2119/98/EC.

# 6. Training

#### 6.1.1. ECDC

Regulation 851/2004/EC (Article 3, paragraph 2b; Article 9, paragraph 6):

#### The Centre shall:

- within the field of its mission, provide scientific opinions and scientific and technical assistance including training;
- support and coordinate training programmes in order to assist Member States and the Commission to have sufficient numbers of trained specialists, in particular in epidemiological surveillance and field investigations, and to have a capability to define health measures to control disease outbreaks.

# 6.1.2. *Summary*

The ECDC has the clear mandate of supporting and coordinating training activities on the community level.

# 7. Response to health threats and events

#### 7.1.1. Commission

Decision 2000/57/EC (Annex II, paragraphs 2.1, 3.1, 4)

#### The Commission:

- may convene an extraordinary meeting of the Network committee or of experts proposed by the committee to coordinate necessary action;
- shall support Member States in coordinating their efforts to cope with the public health threat and to ensure protection of the population;
- inform concerned professionals and the general public of any guidance agreed at Community level and shall inform them without delay when the public health threat is over.

#### 7.1.2. *ECDC*

Regulation 851/2004/EC (Article 3, paragraphs 1 and 2e; Article 5, Paragraph 4; Article 8,

Paragraph 1; Article 9, Paragraph 2; Article 11, Paragraph 2):

#### The Centre shall:

- in the case of other outbreaks of illness of unknown origin which may spread within or to the Community, act on its own initiative until the source of the outbreak is known;
- in the case of an outbreak which clearly is not caused by a communicable disease, act only in cooperation with the competent authority upon request from that authority;
- on request from the Commission, the Member States, third countries and international organisations (in particular the WHO) provide scientific or technical assistance, and mobilising and coordinating investigation teams;

- exchange information, expertise and best practices, and facilitate the development and implementation of joint actions;
- support and assist the Commission by operating the early warning and response system (EWRS);
- support and assist the Commission by ensuring with the Member States the capacity to respond in a coordinated manner;
- carry out technical and scientific evaluation of prevention and control measures at Community level.

#### 7.1.3. *Member States*

Decision 2119/98/EC (Article 4a, e, and f; Article 6)

Member States shall communicate to the Community network:

- information control measures applied regarding the appearance or resurgence of cases of (listed) communicable diseases in the Member State;
- information concerning existing and proposed mechanisms and procedures for the prevention and control of communicable diseases, in particular in emergency situations;
- any relevant considerations which could help Member States to coordinate their efforts for the prevention and control of communicable diseases, including any counter-measures implemented.

#### Member States shall:

- on the basis of the information available through the Community network, consult each other in liaison with the Commission with a view to coordinating their efforts for the prevention and control of communicable diseases;
- before adopting measures for the control of communicable diseases, inform the other Member States and the Commission on the nature and scope of those measures, through the Community network;
- consult other Member States and the Commission through the Community network on the nature and scope of intended measures unless the need to protect public health is so urgent that consultation proves impossible;
- as soon as possible, inform through the Community network the other Member States and the Commission, where the Member State has to adopt, as a matter of urgency, control measures in response to the appearance or resurgence of communicable diseases;
- on the basis of their consultations and the information provided, coordinate among themselves in liaison with the Commission with regard to the measures which they have adopted, or intend to adopt at national level;

Decision 2000/57/EC (Annex II, paragraphs 2, 2.1, 3 and 4)

#### Member States shall:

- inform their counterparts in other Member States and the Commission without delay on the measures they intend to take themselves or in association with other concerned Member States, the Commission or other parties concerning "EWRS events";
- provide field epidemiology expertise, laboratory support, clinical and other essential expertise;
- without delay inform other Member States and the Commission on the progress and results of the measures taken;
- without delay provide suitable information material to concerned professionals and the general public and shall inform them of the measures adopted;

 inform concerned professionals and the general public of any guidance agreed at Community level and shall inform them without delay when the public health threat is over

Regulation 851/2004/EC (Article 4c; Article 18d)

#### Member States shall:

- identify, within the field of operation of the mission of the Centre, recognised competent bodies and public health experts who could be made available to assist in Community responses to health threats, such as field investigations in the event of disease clusters or outbreaks:
- through their representatives in the ECDC Advisory Forum, ensure close cooperation between the Centre and the competent bodies in the Member States in particular where the Centre or a Member State identifies an emerging public health threat.

# 7.1.4. *Summary*

There is a shared responsibility between the Commission, the ECDC and the Member states to act in a coordinated way in case of a major health threat or health event. ECDC will play a strong operational role, by (on request) giving technical support to the Member States in the investigation and control of large outbreaks. All three parties have far-reaching information responsibilities.

On the initiative of the Commission necessary measures could be adopted through an extraordinary meeting of the Network committee.

#### 8. Surveillance

#### 8.1.1. Commission

Decision 2119/98/EC (Article 3a, b, c, d and e))

#### The Commission shall:

- Adopt through the procedures laid down in Article 7 of Decision 2119/98/EC:
  - the communicable diseases to be progressively covered by the Community network;
  - o the criteria for selection of these diseases, having regard to the categories set out in the Annex and the existing collaborative networks for disease surveillance that can be built on:
  - o case definitions, in particular clinical and microbiological characteristics;
  - o the nature and type of data and information to be collected and transmitted by the structures and/or authorities referred to in the second paragraph of Article 1 in the field of epidemiological surveillance and the ways in which such data are to be made comparable and compatible;
  - o epidemiological and microbiological surveillance methods.

#### 8.1.2. ECDC

Regulation 851/2004/EC (Article 3, paragraphs 2a and e; Article 5, Paragraphs 1, 2 and 4; Article

# 11, Paragraphs 1 and 2):

#### The Centre shall:

- search for, collect, collate, evaluate and disseminate relevant scientific and technical data;
- cooperate with the competent bodies recognised by the Member States on collection of data;
- coordinate data collection, validation, analysis and dissemination of data at Community level, including on vaccination strategies;
- developed the statistical element of this data collection in collaboration with Member States using, as necessary, the Community statistical programme, to promote synergy and avoid duplication;
- develop with the competent bodies of the Member States and the Commission appropriate procedures to facilitate consultation and data transmission and access;
- carry out technical and scientific evaluation of prevention and control measures at Community level; and
- work in close cooperation with the competent bodies of the organisations operating in the field of data collection from the Community, third countries, the WHO, and other international organisations.
- coordinate the European networking of bodies operating in the fields within the Centre's mission;
- operate the dedicated surveillance networks;
- maintain the database(s) for such epidemiological surveillance;
- provide quality assurance by monitoring and evaluating surveillance activities of such dedicated surveillance networks to ensure optimal operation;
- harmonise and rationalise the operating methodologies;
  - 8.1.3. Designated surveillance systems

Decision 2003/542/EC (Article 1, annex III)

#### Each designated surveillance systems will:

- collect relevant surveillance data and information;
- ensure coordination within its structure;
- without delay communicate them to the Community network:
- provide the Community network with its operating procedures, addressing at least:
  - o Coordinating structure and decision-making process.;
  - o Project management administration and supervision:
  - o Case definitions, nature, and type of data to be collected;
  - o Data management and protection, including data access and confidentiality;
  - Ways in which data are made comparable and compatible (quality requirements and data validation);
  - Appropriate technical means and the procedures by which the data are to be disseminated and analysed at Community level (data dissemination and reporting);
  - Proposed public health action, infection control procedures, and laboratory procedures;
  - 8.1.4. Member States

Decision 2119/98/EC (Article 4b, c and d)

#### Member States shall:

- communicate to the Community network any relevant information in its possession:
  - o on cases of communicable diseases covered by the categories set out in the Annex,
  - o nnew communicable diseases of unknown origin in non-member countries;
- communicate to the Community network any relevant information concerning the progression of epidemic situations for which it has responsibility for information collection;
- information on unusual epidemic phenomena or new communicable diseases of unknown origin;

Decision 2000/96/EC (Article 6)

#### Member States shall:

- Member States shall disseminate in the Community network relevant information in their possession detected in their national surveillance system on communicable diseases or special health issues selected for epidemiological surveillance not yet covered by dedicated Community surveillance network arrangements;
- disseminated relevant information on communicable diseases not listed in Annex I of the Decision through the Community network whenever this is found necessary in order to protect public health in the Community.

Decision 2002/253/EC (Article 1) with amendment in 2003/542/EC (Article 1)

#### Member States shall:

- for the purposes of submitting data for the epidemiological surveillance and control of communicable diseases under the provisions of Decision No 2119/98/EC apply the case definitions specified in the Annex;
- Member States shall, through their designated structures and/or authorities, specify a contact point for each dedicated surveillance network, delegated to be their national representative to provide data and information

Regulation 851/2004/EC (Article 4a, Article 18, paragraph 4b and d)

#### Member States shall:

- provide to the Centre in a timely manner available scientific and technical data relevant to its mission;
- through their representatives in the ECDC Advisory Forum, ensure close cooperation between the Centre and the competent bodies in the Member States on the following items:
  - o in those circumstances where the Centre and a national body cooperate;
  - o the promoting, starting up and supervising of the European networks within the fields of the Centre's mission.

#### 8.1.5. *Summary*

The ECDC has the full responsibility of coordinating all Community-level surveillance of communicable diseases. A handover of files on surveillance networks will take place as the Commission funding of specific networks run out, starting in 2006. In a transition phase (2005–2007), the ECDC will assume its coordinating responsibilities, through memoranda of understanding with the networks.

The Commission will continue to play an important role in providing the legal framework by adopting necessary measures according to the procedures set up in Decision 2119/98/EC. The Member states have far-reaching responsibilities to provide all necessary surveillance data to the ECDC, to the Community network and the respective surveillance networks.

#### 9. Communication

9.1.1. Commission

Decision 2119/98/EC (Article 3h)

The Commission shall:

- Adopt through the procedures laid down in Article 7 of Decision 2119/98/EC:
  - the appropriate technical means and the procedures by which the data will be disseminated and analysed at Community level.

#### 9.1.2. ECDC

Regulation 851/2004/EC (Article 3, paragraphs 1 and 2c; Article 5, Paragraph 2c; Article

10, Paragraph 2; Article 11, Paragraph 3; Article 12,): The Centre shall:

- within the field of its mission, provide timely information to the Commission, the Member States, Community agencies and international organisations active within the field of public health;
- communicate current and emerging threats to human health from communicable diseases;
- forward to the European Parliament, the Council and the Commission an annual evaluation of the current and emerging threats to health in the Community;
- inform the Commission and Member States as soon as possible about findings of emerging health threats which require their immediate attention;
- communicate the results of the analysis of data from the dedicated surveillance networks and networking activities to the Community network;
- make available relevant data and information to the Member States in an objective, reliable and easily accessible way;
- communicate on its own initiative in the fields within its mission, after having given prior information to the Member States and to the Commission;
- ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information with regard to the results of its work
- make available information for the general public, including through a dedicated website;
- publish its scientific opinions;

- act in close collaboration with the Member States and the Commission to promote the necessary coherence in the risk communication process on health threats;
- cooperate as appropriate with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

# *9.1.3. Summary*

It is a key responsibility of the ECDC to communicate and make available all necessary scientific and technical data from its various activities to the Commission, to the Member States and to other stake holders, including the general public.

### 10. Scientific opinions and guidelines

10.1.1. Commission

Decision 2119/98/EC (Article 3f and g)

The Commission shall:

- Adopt through the procedures laid down in Article 7 of Decision 2119/98/EC:
  - o guidelines on the protective measures to be taken, in particular at external frontiers of the Member States, notably in emergency situations;
  - o guidelines on information and guides to good practice for the public.

10.1.2. ECDC

Regulation 851/2004/EC (Article 3, paragraphs 2a, 2b and 2e; Article 5, Paragraph 4; Article 6;

Article 7, Paragraph 1):

The Centre shall:

- seek to maintain scientific excellence at all times through the best expertise available;
- provide independent expert advice, data and information;
- cooperate with the competent bodies recognised by the Member States, particularly on preparatory work for scientific opinions, scientific and technical assistance;
- within the field of its mission, search for, collect, collate, evaluate and disseminate relevant scientific and technical data;
- issue independent scientific opinions at the request of the Commission, the European Parliament a Member State, or on its own initiative, on matters falling within its mission;
- exchange information, expertise and best practices, and facilitate the development and implementation of joint actions;
- where independent scientific expertise is not available from existing dedicated surveillance networks set up independent ad hoc scientific panels;
- promote and initiate scientific studies necessary for the performance of its mission and applied scientific studies and projects on the feasibility, development and preparation of its activities
- avoid duplication with Member States' or Community research programmes;
- consult the Commission with regard to the planning and priority setting of research and public health studies.

#### 10.1.3. Member States

Decision 2119/98/EC (Article 10) Member States shall foster cooperation with non-member countries and international organisations competent in the field of public health, in particular the World Health Organisation.

Regulation 851/2004/EC (Article 18a, e and f): Member States shall, through their representatives in the ECDC Advisory Forum, support the director in ensuring the scientific excellence and independence of activities and opinions of the Centre, and ensure close cooperation between the Centre and the competent bodies in the Member States on the following items:

- o coherence of the Centre's scientific studies with Member States;
- o the setting up of scientific panels by the Centre;
- o scientific and public health priorities to be addressed in the work programme.

# 10.1.4. Summary

The ECDC will through its internal procedures issue independent scientific opinions, advice and technical guidelines. Whenever necessary, the Commission could use these guidelines as a basis for draft decisions to be adopted through the procedures set up under Decision 2119/98, or ask the ECDC to assist in the drafting of new guidelines.

# Annex 4: Indicative list of tasks to be conducted over the years by Commission services (C), ECDC (E) or shared (E/C or C/E)

Activity/Year	2005	2006	2007	2008
General cooperation				
Report to the Council and Parliament on the performance of the Community network, and propose changes as appropriate	С	С	С	С
Health Measures				
Propose and adopt legal measures, in particular under 2119/98	С	С	С	С
Check the correct application of legal measures by MS	С	С	С	С
Suggest technical content for measures, advise and support the Commission	(E)	Е	Е	Е
Risk identification and risk assessment				
Technically operate the EWRS	С	E	E	Е
Analyse the content of messages received via the EWRS	C/E	E/C	E/C	E/C
Assess the use of EWRS and report on operations	C/E	E/C	E	E
Link the EWRS with other Community alert systems	С	E/C	E/C	E/C
Forward to the Parliament, the Council and the Commission an annual evaluation of current and emerging health threats in the Community	-	E	E	E
Collect, verify and asses epidemic intelligence information	C/E	E/C	E	Е
Inform about finding requiring immediate attention	C/E	E/C	E/C	E/C
Provide information, expertise, advice and risk assessment	(E)	E	Е	Е
Communicate information to all stake holders, including the public	(E)/C	E/C	E/C	E/C
Preparedness and planning				
Adopt guidelines on protective measures and procedures for coordination (Commission Decisions under 2119/98)	С	С	С	С
Coordinate policy decisions on preparedness planning with MS	С	С	С	С
Establish procedures and tools to mobilise human resources and expertise	C/E	E/C	Е	E
Ensure with the MS the capacity to respond in a coordinated manner	E/C	E/C	E/C	E/C
Coordinate technical aspects of health sector preparedness with MS	E/C	E	E	Е
Provide scientific and technical expertise to MS on preparedness planning and development of intervention strategies	E/C	E	E	E
<u>Training</u>				
Contractual responsible for EPIET	С	C/E	C/E	Е
Support and coordinate other training programmes within scope of the Centre	(E)	Е	Е	Ε

# Response to health threats and events

Coordinate policy making on response with MS	С	С	С	С
Establish procedures and tools to mobilise human resources and expertise	C/E	C/E	Е	Е
Act on outbreaks of unknown origin on own initiative	C/E	Е	E	Е
On request provide scientific and technical assistance on other outbreaks	E	Е	E	Е
On request mobilise and coordinate outbreak investigation teams	E	Е	E	Е
Give scientific opinions (own or through scientific panels)	Е	Е	Е	E
Prepare guidelines and recommendations for application of prevention and control measures	(E)/C	E/C	E	E
Technically and scientifically evaluate prevention and control measures	(E)	E	E	E
Surveillance				
Manage public health programme budget	С	С	С	С
When necessary, adopt or revise case definitions and other procedures, on advice from ECDC (procedures under 2119/98)	С	С	С	С
When necessary, adopt new criteria or revise existing for selection of diseases under surveillance, on advice from ECDC (procedures under 2119/98)	С	С	С	С
Fund + manage contracts of now ongoing surveillance networks (coordinated with ECDC)	С	С	С	-
Operate the surveillance networks in a coordinated manner, as their current contracts run out	(C)	E	E	E
Further enhance the performance of EU-wide surveillance and laboratory data	(C)	E	E	E
Encourage cooperation between expert and reference laboratories	(E)/C	E/C	E/C	E/C
Communication				
Be contractually responsible for Eurosurveillance	С	С	C/E	E
Issue a weekly epidemiological bulletin	E	E	E	E
Communicate data and information widely on all areas within its responsibility, using appropriate channels	E/C	E/C	E/C	E/C
Scientific opinions and guidelines				
Adopt guidelines on protective measures and procedures for coordination (Commission Decisions under 2119/98)	С	С	С	С
Issue independent scientific opinions	Е	E	E	E
Set up independent scientific panels	Е	E	E	E
Promote and initiate necessary scientific studies	Е	Е	E	E
Take over scientific work on focus areas from Commission: Antimicrobial resistance, VPD, Healthcare-associated infections	(E)/C	E	E	E
Consult the Commission with regard to planning and priority setting of research and public health studies	E	E	E	E