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**Tasks and role of the European Commission in outbreak investigation, communicable disease surveillance and Health Security**

**Submitted by the Netherlands**

**Intra-EU Activities**

1. The Commission is responsible for **coordinating** (e.g. putting into appropriate relationship the authorities responsible for operations on) epidemiological surveillance on disease outbreaks between the Member States. The Commission has laid down rules on priority diseases, notifications, case definitions, development of surveillance schemes and networks on the basis of European Parliament and Council Decision 2119/98/EC setting up a European Network for the Epidemiological Surveillance and Control of Communicable Diseases (Annex I). It operates a Network of surveillance structures (public health institutes/agencies and public health authorities) of the EU Member States for this purpose. The Commission is not, however, responsible for the operational surveillance and management of disease outbreaks and crises;
2. The Commission is also responsible for receiving and disseminating to the EU Member States official notifications of outbreaks and for facilitating information sharing and mutual consultation of Member States on counter-measures (such as travel advisories, border control and screenings, restriction of movement such as quarantine, etc.) using the Early Warning and Response System (EWRS) of the EU which is comprised of the Commission and of the competent authorities of the Member States responsible for the measures to be taken on communicable diseases and outbreaks of unknown origin;
3. The Commission must also check that the Member States apply a EU Council Directive on restrictions of movement by Member States on foreign nationals on their territory on the grounds of public health which have to be fully justified and proportional and do not discriminate against foreign nationals;
4. The Commission promotes, through funding of the health security programme, actions and projects under the 2003-2008 public health programme of the EU, the coordination of preparedness and response of Member States to deliberate releases of biological and chemical

agents. In this context, the Commission has also set up jointly with EUROPOL a training module on interaction between Public Health and Law Enforcement to develop understanding of relevant laws and common approaches, using a "train-the-trainers" strategy;

5. The Commission operates the RAS-BICHAT alert system for bio-terrorism and chemo-terrorism, a secure 24 hour/7 day-a-week rapid alert system. This system is operational since June 2002 and links the members of the Health Security Committee and also permanent contact points in all the Member States. It hooks up with alert systems on risks related to the EWRS (communicable disease outbreaks, food, feed, animals and plants and the Civil Protection mechanism);

6. The Commission operates also the system MediSys which scans publications and news Websites on the WWW for items that may indicate something untoward and provide advance warning of an outbreak or malicious release before it becomes an emergency let alone degenerate into a crisis (i.e. loss of confidence in the ability of the authorities to exercise control). Links are maintained with the WHO's outbreak verification facility and efforts are being undertaken to establish links with the US Department of Health and Human Services network and Canadian GPHIN (Global Public Health Information Network);

7. The Commission coordinated, using the EWRS, the SARS and Avian Influenza responses in the EU in close cooperation with the WHO;

8. The Commission has tabled for consultation in the EU in March 2003 a working paper on preparedness and response planning for pandemic influenza;

9. The Commission will table a working paper on general preparedness and response planning for public health emergencies of EU concern;

10. The public health programme of the EU, administered by the Commission, funds, in addition to actions on health security, projects for cooperation in surveillance, laboratory collaboration (P4 labs and other pathogen labs), vaccine and other public health medicines development strategies, anti-microbiological resistance, field epidemiological training (EPIET) and publications (EUROSURVEILLANCE) etc;

11. The European Union will further enhance capabilities in this field by the establishment of the European Centre for Disease Prevention and Control which will become operational in May 2005

12. The European Community has legislation in force under the policies on health and safety at work and on environmental protection related to genetically modified organisms. Rules exist for technical harmonization and standardisation based on this legislation. The legislation is regularly adapted to technical progress, changes in international regulations or specifications and new findings. The bio-safety and health and safety at work Community legislation aims to reduce risks related to storage, and manipulation of pathogenic agents to levels of risk that are not significant from the health point of view. It also relates to the protection of, environmental compartments with measures such as, adequate containment levels – rules for conduct – general and or personal protection measures, notification procedures and health surveillance measures.

There are specific provisions for competences and qualifications, training and required experience to increase the safety of manipulating pathogenic agents.

13. The Commission proposed amendment to the pharmaceutical EU-legislation on liability for non-authorised products for bio-terror-related purposes.

### **International Activities**

14. The Commission is a founding and full partner in the Global Health Security Initiative initiated 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 co-operation (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. An incident scale for risk communication and algorithms for response in various scenarios have been agreed between the parties to the initiative, workshops on smallpox training-the-trainers, smallpox vaccines and patient isolation have been held, inter-laboratory tests have been carried out, groups on laboratory collaboration, risk communication and co-ordination, field investigation, chemical events and influenza have been formed. The Commission participated in and learned from the smallpox plan evaluation exercise (Global Mercury) conducted in September 2003. Ministers and the Commissioner meet regularly to review progress.

15. The Commission has taken various actions to address the recent outbreaks of SARS and avian influenza in Asia and will take further measures and initiatives to guard against the introduction of such emerging risks from zoonotic diseases.

16. The Commission received from the Council the authorisation to open the negotiation at EU-level on the revision of the International Health Regulations under the framework of the WHO.

### **Health Security: Public Health Preparedness and Response**

17. The action in the health field is intended to cover the whole spectrum of activities from risk assessment via the detection or exclusion of presence of biological, chemical or radioactive agents in packages, environmental compartments or humans, animals or plants, through to risk communication between health authorities, health professionals and the public, to risk management involving the introduction or application of counter-measures including travel advisories, screenings and contact tracing, vaccination, decontamination, mass casualty triage, treatment, isolation, quarantine, interdiction of premises and movement, and waste disposal. As such, alert systems and coordination of measures ensured by the Health and Consumer Protection Directorate-General apply over a much wider range of incidents than for other domains with alert mechanisms and interventions that apply to large-scale disasters. They apply from simple threats or suspicion of a deliberate release to cause harm or identification of suspect cases from outbreaks or contamination that do not fit the "natural background" all the way up to mass casualties and interdiction of movement which may require law enforcement and civil protection interventions.

18. Work on health security at EU level is not finished by any means. A communication (COM (2003) 320) on progress with the implementation of the health security programme was published on 2 June 2003; Community action has already produced valuable and promising results. However it is an ongoing process to adapt to developments and events.

19. This paper provides hereafter a view on a selection of Community actions in the field of Health Security that shows the co-ordination and co-operation arrangements put in place, but also points out that continuous efforts and adaptations are needed as demonstrated in some issues where an accelerated co-operation would support the solidarity with an adequate and timely answer to the effects of deliberate (terrorist attacks) or natural releases of biological / chemical agents.

20. Deliberate releases of biological and chemical agents to cause harm can be overt, with effects and victims immediately apparent, or covert, in which widespread contamination of people and the environment can occur before effects become manifest. Mitigating the effects of such releases requires early detection of the agents implicated and case recognition of those affected. Only then can a multi-sector response be activated and its success will depend on the speed and accuracy of the agent detection and case identification. A lot of activities have been achieved under the programme and the efforts continue with respect of some issues like:

- (a) A secure 24 hour/7 day-a-week rapid alert system (**RAS-BICHAT**), has been set up and is operational since June 2002. The system links the members of the Health Security Committee and contact points designated by its members to provide round the clock coverage and urgent consultations in an emergency. It is linked to and complements the system established by 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. It hooks up with alert systems on risks related to communicable disease outbreaks, food, feed, animals and plants as well as the new Europol Rapid Alert System;
- (b) Monitoring of Web-based information to provide advance warning of suspicious circumstances or outbreaks: A system (MediSys) is set up with links to existing systems under the External Relations Directorate-General of the Commission, the Joint Research Centre and the Canada Global Public Health Information Network;
- (c) An improved cooperation and communication mechanism with G7 countries (the unit being the entry point for the Commission in the Global Health Security Action Group)
- (d) Case definitions for bio-terror agents, laid down in Commission Decision 2003/534/EC of 17 July 2003;
- (e) A matrix model has been developed and used on a restricted basis for prioritising bio-terror agents and actions on bioterrorism and modelling for bioterrorism emergencies is being funded;
- (f) A tool to evaluate and classify the severity of an incident has been developed and is included in the RAS BICHAT system; Laboratory assistance: A network of high security laboratories has been formed consisting of laboratories in the Member States and a ring test and a quality assurance project are being prepared. Networks including laboratories for other high and medium-level pathogens are also in the planning phase. Co-ordination and evaluation of emergency plans: Exchanges on smallpox emergency plans have been organised with Member States' experts and smallpox plans of all 15 have been collected

and shared. A table has been compiled comparing corresponding measures and alert levels.

- (g) A framework for an expert directory with information on relevant expertise in the different MS has been developed and production of the directory is in progress;
- (h) 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 the EU's Poison Centres are been linked into a surveillance network;
- (i) An incident investigation and environmental sampling group has been formed to develop EU-wide protocols and share good practice and know-how;

#### Scenario building and training (exercises)

21. It has now become a priority under the Health Security programme to intensify work on emergency planning and promote modelling, so as to permit the refinement and strengthening of emergency and strategic plans for threats and attacks.

22. Exercises at the EU level and internationally (Global Health Security Action Group, G7+ Mexico) showed that the process of adjusting and complementing emergency plans or devising new ones is not yet complete, with some Member States more advanced than others. Emergency plans, tested with exercises ensuring the smooth interdisciplinary working between clinicians, microbiologists, toxicologists, epidemiologists, communicable disease control physicians, and radiation biologists and physicists with the civil protection, security and law enforcement services would provide a high degree of confidence in the capacity to mount a proportional multi-sector response.

23. An EU- wide exercise, to test communication channels and evaluation of existing emergency plans will be conducted during an exercise for biological and chemical release events that is scheduled for 2004-2005.

24. A central element in the efforts to facilitate the obligations to organise mutual assistance is identification of needs for further EU co-ordination across the whole spectrum of policies that would be affected by a global health emergency, such as a smallpox outbreak, and the consolidation of responses within an overall EU plan.

#### Issuance of the Directory of Experts for Health Sector Assistance

25. The European Union is a border-free space in which products, services and people can circulate without hindrance. It is essential in such a space that appropriate arrangements be put in place to ensure prompt and secure notification and exchange of information in case of threats and attacks, action at source be undertaken to stem the spread of disease and environmental contamination, mutual assistance be provided for diagnosis and management of cases, access to special laboratory services and expertise for epidemiological investigations be secured, and public health responses be put into effect. This, in turn, requires sharing of knowledge and good practice, laboratory facilities, equipment and products, experts and intervention personnel across the Member States of the EU, as well as good co-ordination and interoperability of preparedness and response plans.

26. Knowledge about bio-terror agents and corresponding diseases and their clinical and epidemiological management and associated laboratory analysis is limited. Hence the need to identify relevant experts in the EU and list them in a Directory to be shared by the authorities of the Member States will contribute to the mutual assistance under the Solidarity obligation. A Directory of experts for advice and assistance has already been set up but it requires from the Member States more information on the resources available and willing to participate in their respective country.

### **Conclusion**

27. The mechanisms put in place for deliberate releases complement the mechanisms which strengthen the preparedness and response of the Community to public health threats, such as the instruments with regard to the Communicable Disease Community Network (European Council and Parliament Decision 2119/98/EC of 24/09/98, OJ L 268, 3.10.1998, p. 1). This enlarged scope in the public health field will contribute to the efforts of the Member States to foster mutual assistance in the Union. To obtain the desired effect of mutual assistance between the Member States, the current Public Health actions and instruments have to operate in conjunction with efforts made in other Community sectors and policy areas.

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