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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

REPORT ON THE OPERATION OF THE EARLY WARNING AND RESPONSE SYSTEM OF THE COMMUNITY NETWORK FOR THE EPIDEMIOLOGICAL SURVEILLANCE AND CONTROL OF COMMUNICABLE DISEASES (DECISION 2000/57/EC) DURING 2002 AND 2003

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1. TERMS OF REFERENCE

Decision 2000/57/EC[1], on the Early Warning and Response System (EWRS) for the prevention and control of communicable diseases, states that the Competent Authorities in Member States shall submit yearly, not later than 31 March, an analytical report of the events and procedures applied within the early warning and response system *(Article 3.1)*. It states also that the Commission shall, on the basis of the reports, examine in an annual report the operation of the Early Warning and Response System and if necessary propose changes thereto *(Article 3.2)*.

The Annual Reports from the member states and the preparation of the related Commission report 2002 were delayed due to the work overload caused by the SARS event which developed abruptly starting on mid March 2003. Priority activities in the responsible Commission service, related to the event and to the preparation to a possible new outbreak, lasted until late summer 2003. This document of the Commission reports on the operation of EWRS during 2002 and 2003. It draws conclusions from the reports submitted by the Member States and experiences with the operation of EWRS during the period in question.

This report is supported by a Commission Staff Working Paper (CSWP) providing more detailed technical information on the events communicated to EWRS.

2. LEGAL BASIS OF THE EWRS

The European Parliament and Council Decision 2119/98/EC[2] has established EWRS as a function of the Community Network for the epidemiological surveillance and control of communicable diseases. Decision 2000/57/EC states that the EWRS is reserved to events endowed with Community relevance, as specified in its Annex I, and establishes the EWRS operational procedures.

3. REPORT ON THE OPERATION OF EWRS IN 2002

The information on the operation of EWRS during the year 2002, as provided by the Member States, can be summarised as follows.

3.1. Events notified

The events notified to EWRS during 2002 number fifty-two. They include all the messages delivered by means of the information exchange application present in the web site of the Health Surveillance System on Communicable Diseases (HSSCD) excluding test and service messages.

An analysis of the **52 event notifications** indicated that 41, i.e. **79%** of the events, were notified with messages sent as plain information, while 10 (**19%)** of the events were reported in the "information exchange" level actually activating an Early Warning (activation level 1). One event (**2%**) was notified as an Early Warning at

[1] OJ L21, 26.10.2000, p.32
[2] OJ L268, 03.10.1998, p.1

activation level 2 and **none** as a level 3. The timeliness of the notification to EWRS and the size of the outbreak at the time of notification were noted, if available. About 60% (18 outbreaks) of the 32 outbreaks occurring in the EU Member States were notified within 35 days from the outbreak onset and with an outbreak size of less than 93 cases.

3.2. Response to early warnings

Information on the actions undertaken by Member States after reception of an outbreak notification was not regularly communicated to EWRS. A few Member States authorities forwarded the information to the appropriate departments and structures in their country, after evaluation of the information received through EWRS. Only in a few cases specific measures were taken, because most outbreaks, although with potential Community relevance, were controlled with standard local or national measures. Three outbreaks required a more complex response, involving contacts between health authorities of different Member States: an outbreak of pericarditis-myocarditis in Greece, outbreaks of viral gastroenteritis linked to permanence in Andorra and, finally, an outbreak of salmonellosis (*S. cerro*) in Belgium (with cases also in France).

3.3. Updates and deactivation of the system

Updates on on-going outbreaks were communicated rarely. Only in one event (pericarditis-myocarditis in Greece) updates to EWRS were frequent and the last one indicated the likely end of the outbreak. This event had drawn much attention from the health authorities of other EU Member States.

4. REPORT ON THE OPERATION OF EWRS IN 2003

The information on the operation of EWRS during the year 2003, as provided by the Member States, can be summarised as follows.

4.1. Events notified

The events notified to EWRS during 2003 number **forty-one** (excluding test and service messages). They include all the messages delivered by means of the information exchange application present in the web site of the Health Surveillance System on Communicable Diseases (HSSCD).

An analysis of the **41 event notifications** indicated that 23, i.e. **56%** of the events, were notified with messages sent as plain information, while 15 (**37%)** of the events were reported in the "information exchange" level actually activating an Early Warning (activation level 1). Two events (**5%**) were notified as an Early Warning at activation level 2 and **one** (**2%**) at activation level 3. Records of the timeliness of the notification by Member States to EWRS and the size of the outbreak at the time of notification indicated that about 60% (14 events) of the 25 events occurring in the EU were notified to the EWRS within 14 days from the onset of symptoms in the index case and in association of outbreak sizes of less than 15 confirmed cases.

4.2. Response to early warnings

Information on the actions undertaken by Member States in response to an outbreak notification issued by another Member State was not always communicated to EWRS. According to the information available, however, in most notified events, specific control measures were not undertaken by the Member States in response to a notification. The Netherlands communicated that all early warnings, except the heat-related deaths in France, were mentioned in the minutes of the weekly reporting meeting at the National Institute of Public Health and the Environment. These minutes are sent to most public health services and medical microbiologists in the Netherlands. Austria communicated that EWRS-messages were delivered via the "Early Warning Austria" – E-Mail system to the regional public health boards who then transmit the messages to the district Public Health officers. EWRS messages are simultaneously reported to the reference centres and Ministry of Health departments concerned.

Two outbreaks required a more complex response, or stimulated some specific actions: the SARS event, which represented a major threat to the EU and required a coordinated effort by all Member States, and the outbreak of gastroenteritis in a cruise ship, which required urgent contacts among health authorities and raised some questions beyond its actual public health threat.

4.3. Updates and deactivation of the system

Messages to provide updated information to the EWRS on on-going outbreaks, including deactivation of the system, were rarely sent. The system, however, was extensively used for updates on the epidemiological situation and for the exchange of information on measures during the SARS event.

5. PROTECTION OF PERSONAL DATA

Decision 2119/98/EC establishes that Member States have to provide a series of information of relevance to the surveillance and control of communicable diseases, including information on their occurrence, the progression of the epidemic situation, as well as on intended or adopted measures for the control or prevention of these diseases. The exchange of data which could be regarded as personal data has never occurred during the operation of the EWRS. However it is a matter of fact that exchange of personal data among the members of the EWRS may prove necessary for the implementation of emergency control actions involving coordination among Member States. The EWRS should be ready to process personal data in compliance with the Community legislation, namely Directive 95/46/EC[3], which is addressed to the Member States, and Regulation 45/2001/EC[4] which applies to Community Institutions and bodies. Such data may include information on personal health status as far as these data are necessary for the implementation of effective and coordinated public health control actions.

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[3] OJ L281, 23.11.1995, p. 31

[4] OJ L8, 12.01.2001, p. 1

An analysis of the EWRS structure and function with reference to the requirements of the Community legislation, can be summarized as follows:

(1) Decision 2119/98/EC provides a basis for allowing the handling of personal data in the Community Network, which is made up by public health authorities identified in the said decision.

(2) The components of the Community Network for the surveillance and control of communicable diseases, are identified as follows:

(a) The controller, which is the Commission service tasked with the implementation of Decision 2119/98/EC.

(b) The owner of the system, which is the Commission service that is mandated with the implementation of Decision 2119/98/EC, and runs the Health Surveillance System for Communicable Diseases (HSCCD) application for the exchange of information in the context of EWRS.

(c) The processors:

- The members of the Community Network (the structures/authorities designated by the Member States), who make data available.
- The Commission service tasked with the implementation of Decision 2119/98/EC.
- The EWRS and the HSSCD webmasters, who implement the access rules and the maintenance of the application.
- The Commission's Data Centre, which stores the data on behalf of the Commission service that is tasked with the implementation of Decision 2119/98/EC.

(d) The recipients:

- The Commission,
- The members of the Community Network (the structures/authorities designated by the Member States),
- Any other person or organization to which such data need to be disclosed for the implementation of public health protection and disease control measures.

(3) Collection of national surveillance data in the Member States has to comply with the national legislation implementing Directive 95/46/EC. This data collection is performed according to national provisions and is not in the scope of the Decision 2119/98/EC. In the notification to their Data Protection Officer, the national authorities responsible for the collection of such data have to indicate that data are transferred to the Community Network pursuant

to Decision 2119/98/EC by means of an IT tool (HSSCD) provided by the Commission.

(4) The Commission service tasked with the implementation of Decision 2119/98/EC has to adopt measures to ensure a level of security appropriate to the processing of health data (art. 10 of Regulation 45/2001) in the Community Network, in compliance with art. 22 Regulation 45/2001. To this end, the features of the system have been analyzed with reference to the security requirements of Regulation 45/2001/EC, with the findings that organizational and technical security measures can be implemented to:

- improve the control of the access to information;
- enhance the security of some communication procedures of the information exchange tool (HSSCD);
- improve the handling of information received through the EWRS.

To allow the exchange of personal data, when necessary, within the activities of the EWRS, the measures that are related to the areas for improvement indicated in item 4 above have been implemented and a notification to the Data Protection Officer of the Commission made in compliance with art. 25 of Regulation 45/2001/EC. Internal rules for the handling of messages in compliance with Regulation 45/2001/EC have been prepared and implemented in the Commission Unit charged with the operation of EWRS. Moreover, in their quality of recipients of the information provided by the Community system, the public health authorities of the Member States have to document the implementation of guidelines for the handling of information received through the EWRS.

6. CONCLUSIONS

6.1. General comments

Analysis of the content of messages transmitted through EWRS indicates that notifications are sometimes delayed with respect to the date of onset of the event. This is because Member States have to be certain about the facts and about Community relevance before making formal notifications via the EWRS. Analysis of the content of messages transmitted through EWRS in 2002 and 2003 indicates that a gradual but clear improvement in the notification process is taking place. In 2002 many notifications referred to events that had already been characterised or even filed. For a number of events notified in 2003, the delay of notification may be related to the time necessary for the collection of sufficient evidence to allow meaningful conclusions from the analysis of the data. To improve timeliness of notifications, a check-list of criteria for the assessment of Community-relevant events, in compliance with Annex I of Decision 2000/57/EC, has been introduced in 2003. Application of the list facilitates a more uniform and timely notification of events to EWRS. The notification to EWRS of cases of SARS, an event which dominated EWRS activity during 2003, with clear Community relevance, was very rapid.

The SARS event represented a significant test for the usefulness of EWRS. EWRS fulfilled effectively its institutional function, not only with the timely circulation of the alert among the national authorities, but also by facilitating the exchange of information, the provision of technical-scientific advice and the formulation of common positions among the national public health authorities. The consultation platform provided by EWRS was very much appreciated by the authorities of the Member States and resulted in consistent national decision making for the control of the disease. A more detailed analysis of the performance of the system during this event is given below.

The SARS outbreak also demonstrated the utility and flexibility of the new mechanism of the Scientific Support to Policies present in the 6th Framework Programme for RTD[5]. The Extraordinary Council of Health Ministers meeting held on 6 May 2003 called on the Commission to financially support research and development of validated diagnostic test, therapeutic interventions and vaccines. A special call was published on 3rd July 2003 just two months after the Council of Ministers meeting with the aim of developing an EU capability for strategic use of R&D resources against SARS and in the event of similar outbreaks. This call was the result of intense discussions among Commission services and relevant experts in this field including the SARS Expert Group. Seven research projects were funded with an ad hoc EU research budget, amounting to about 13.6 M€. Details of EU funded projects can be found at: *http://www.cordis.lu/lifescihealth/ssp.htm.*

The messages on the events notified in 2002 and 2003 do not indicate which criterion, among those indicated in Annex I of Decision 2000/57/EC, had been considered relevant by Member States when reporting. Indicating the relevant criterion for notification by the notifying authority is important for evaluating the relevance and functionality of the criteria as well as their consistent application. Efforts are being made to ensure that such indications are provided.

In 2003 the EWRS has been used occasionally by the national health authorities as a working tool for the exchange of different types of information, as exemplified by messages related to events 12 (poultry influenza in the Netherlands), 28 (West Nile virus in France), and 33 (influenza in EU). However, the use of EWRS as a practical tool to provide and receive information, with the aim of improving awareness and knowledge about events in a framework of co-operation among national public health authorities, was still not fully exploited. The reasons for this are being considered with the authorities of the Member States and conclusions will be drawn on improvements needed.

Analytical annual reports of the events and on the EWRS procedures applied and additional reports on specific events of particular significance have been provided by some Member States in compliance with art. 3 of Decision 2000/57/EC but not by all. It is felt by some that such reports duplicate initial notifications and reports. There is clear preference for additional reporting on specific events only where there is added value besides that provided by the initial notification and report.

This, together with a number of operational improvements that are deemed necessary are under active consideration.

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5 OJ L294, 29.10.2002, p.1

6.2. Lessons learned in the SARS event

During the SARS outbreak the EWRS has proved useful in various ways.

The system provided a unique tool to circulate reliable information quickly to the Commission and to the members of the EWRS.

Especially during the first phase of the event, the EWRS was able to pick up a very early and specific notification on a real and very serious threat.

The content of messages circulated during the SARS outbreak comes under two categories:

- First, those reporting the measures undertaken by the Member States to control the spread of SARS provided the most useful information to co-ordinate the response to SARS at national and at EU level.

- Second, case and update reports provided useful and additional information and they were consistent with those published afterwards by the WHO.

Member States found these messages very helpful and requested that situation reports providing an assessment for decision makers should be made available in the future.

The nature and magnitude of the event caused a very big and rapid flow of messages. Starting from the second week of the outbreak, this situation caused an overload of the EWRS mailbox and had a negative impact on processing and interpreting data on control activities. The problem was solved by creating a specifically dedicated functional mailbox for selected messages (e.g. Case and update report, official communications, call for meetings and consultation teleconferences etc.). Afterwards a special operational mode was set up to confine communications and coordination activities during special events which require intensive and prolonged information exchange.

Following these improvements, it is expected that the EWRS should guarantee exchange of information among EWRS members in an efficient way during future global alerts or during an emergency situation.