COMMISSION DECISION

of 17 July 2003

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

(notified under document number C(2003) 2301)

(Text with EEA relevance)

(2003/534/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community [1], and in particular points (a) and (c) of Article 3 and Article 8 thereof,

Whereas:

(1) Decision No 2119/98/EC provides for the establishment of a network at Community level to promote cooperation and coordination regarding the prevention and control of certain categories of communicable diseases referred to in that Decision. Diseases caused by agents specifically engineered for the purpose of maximising morbidity and/or mortality upon deliberate release should be covered by that Decision.

(2) 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 [2], lists certain communicable diseases to be covered by epidemiological surveillance in the Community network set up under Decision No 2119/98/EC.

(3) 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 [3], provides for case definitions for communicable diseases listed in Decision 2000/96/EC.

(4) It is appropriate that the communicable diseases for which case definitions are provided in Decision 2002/253/EC are congruent with the communicable diseases listed in Decision 2000/96/EC.

(5) Smallpox could pose a serious public health threat in the event of deliberate release. This communicable disease should therefore be listed in Annex 1 to Decision 2000/96/EC. A case definition for smallpox should be included in Decision 2002/253/EC.

(6) Although tetanus is not transmissible among humans and only occurs sporadically in the Community, evaluation of vaccine programmes based on surveillance would contribute to the improvement of vaccine policies. Tetanus should therefore be listed as a communicable disease in Decision 2000/96/EC. A case definition for tetanus is already provided for in Decision 2002/253/EC.

(7) A deliberate release of anthrax in the Community would pose a serious risk to public health. Therefore that disease should be listed as a communicable disease in Decision 2000/96/EC. A case definition for anthrax is already provided for in Decision 2002/253/EC.

(8) Transmission of botulism is not restricted to foodborne intoxication and any reference to that mode of contracting the disease should, therefore, be deleted.

(9) It is appropriate that the case definition for diphtheria in Decision 2002/253/EC be reviewed to take into account the latest scientific evidence.

(10) Decision 2000/96/EC defines criteria for the selection of communicable diseases of special areas to be covered by epidemiological surveillance within the Community network set up under Decision No 2119/98/EC. Q-fever and tularaemia would fulfil those criteria in the event of deliberate release. Those diseases also occur naturally within the European Community. Surveillance based on case definitions would offer added benefit. Those communicable diseases should therefore be listed in Decision 2000/96/EC. In addition, case definitions for Q-fever and tularaemia should be included in Decision 2002/253/EC.

(11) Decisions No 2119/98/EC, 2000/96/EC and 2002/253/EC should therefore be amended accordingly.

[1] OJ L 268, 3.10.1998, p. 1.
[2] OJ L 28, 3.2.2000, p. 50.
[3] OJ L 86, 3.4.2002, p. 44.

(12) The measures provided for in this Decision are in accordance with the opinion of the Committee set up by Article 7 of Decision No 2119/98/EC,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision No 2119/98/EC is amended in accordance with Annex I to this Decision.

Article 2

Annex I to Decision 2000/96/EC is amended in accordance with Annex II to this Decision.

Article 3

The Annex to Decision 2002/253/EC is amended in accordance with Annex III to this Decision.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 17 July 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

In the Annex to Decision No 2119/98/EC, the last indent is replaced by the following:

'— Other diseases (rabies, typhus, viral haemorrhagic fevers, malaria and any other as yet unclassified serious epidemic disease, including diseases that are caused by agents specifically engineered for the purpose of maximising morbidity and/or mortality upon deliberate release, etc.).'

ANNEX II

Annex I to Decision 2000/96/EC is amended as follows:

1. in point 2.1, the following terms are added:

   'Smallpox

   Tetanus';

2. in point 2.4, the term 'Anthrax' is inserted before the term 'Botulism';

3. point 2.5.3 is amended as follows:

   (a) the term 'Q-fever' is inserted after the term 'Echinococcosis';

   (b) the term 'Tularaemia' is added.

ANNEX III

In the Annex to Decision 2002/253/EC, the section on case definitions is amended as follows:

1. The heading 'BOTULISM, FOODBORNE' is replaced by the heading 'BOTULISM'.
2. The text on 'DIPHTHERIA' is replaced by the following:

'DIPHTHERIA

Clinical description

Clinical picture compatible with either respiratory diphtheria, i.e. an upper respiratory tract illness characterised by an adherent membrane of the tonsils, pharynx or nose, in combination with sore throat and low grade fever, or non-respiratory diphtheria; i.e. an illness characterised by cutaneous, conjunctival, otic, genital or other types of ulcers.

Laboratory criteria for diagnosis

Isolation of diphtheria toxin-producing corynebacteria (typically *Corynebacterium diphtheriae* or *C. ulcerans*) from a clinical specimen.

Case classification

Possible:	N.A.
Probable:	a clinically compatible case.
Asymptomatic carriers:	asymptomatic carriers with toxigenic strains.
Confirmed:	a clinically compatible case that is laboratory confirmed with the isolation of a toxigenic strain of corynebacteria, or a clinically compatible case with an epidemiological link to a laboratory confirmed case.

It is to be noted that both respiratory and non-respiratory diphtheria cases with isolation of toxigenic strains should be reported, as should asymptomatic carriers with toxigenic strains, if they are detected. Cases with non-toxigenic *C. diphtheriae* or *C. ulcerans* should not be reported.'

3. After the text on 'POLIOMYELITIS, PARALYTIC' the following is inserted:

'Q-FEVER

Clinical description

A febrile illness accompanied by rigors, myalgia, malaise, and retrobulbar headache. Severe disease can include acute hepatitis, pneumonia, meningoencephalitis and abortion. Clinical laboratory findings may include elevated liver enzyme levels and abnormal film findings.

Laboratory criteria for diagnosis

— isolation of *Coxiella burnetii* from a clinical specimen,

— demonstration of a specific antibody response,

— demonstration of *C. burnetii* in a clinical specimen by detection of antigen or nucleic acid.

For probable cases: a single high titre of specific antibodies.

Case classification

Possible:	N.A.
Probable:	a clinically compatible case that fulfils the laboratory criteria for a probable case or has an epidemiological link.
Confirmed:	a laboratory confirmed case that is clinically compatible or has an epidemiological link.'

4. After the text on 'SHIGELLOSIS', the following is inserted:

'SMALLPOX

Clinical description

An illness with acute onset of fever over 38 °C followed by a rash characterised by vesicles or firm pustules at the same stage of development without other apparent cause and with a predominantly centrifugal distribution.

Atypical presentations may include:
— haemorrhagic lesions,
— flat velvety lesions not appearing as typical vesicles nor progressing to pustules.

Laboratory criteria for diagnosis

Isolation of smallpox (*Variola*) virus from a clinical specimen.

Polymerase chain reaction (PCR) identification of *Variola* DNA in a clinical specimen, followed by sequencing.

Negative-stain Electron microscopy (EM) identification of *Variola* virus in a clinical specimen.

Case classification

Possible:	a clinically compatible case A case that has an atypical presentation and has an epidemiological link to confirmed or probable cases.
Probable:	a clinically compatible case with either identification of orthopox virus by EM or PCR, or an epidemiological link to other probable or confirmed cases.
Confirmed:	for an initial case, a clinically compatible case with laboratory confirmation by EM and PCR, followed by sequencing.

During an outbreak, a clinically compatible case with an epidemiological link and, where possible, laboratory confirmation by either EM or PCR.'

5. After the text on 'TUBERCULOSIS' the following is inserted:

'TULARAEMIA

Clinical description

Clinical picture compatible with one of the different forms of tularaemia:
— ulceroglandular (cutaneous ulcer with regional lymphadenopathy),
— glandular (regional lymphadenopathy with no ulcer),
— oculoglandular (conjunctivitis with preauricular lymphadenopathy),
— oropharyngeal (stomatitis or pharyngitis or tonsillitis and cervical lymphadenopathy),
— intestinal (intestinal pain, vomiting, and diarrhoea),
— pneumonic (primary pneumonic disease),
— typhoidal (febrile illness without early localising signs and symptoms).

Laboratory criteria for diagnosis

— Isolation of *Francisella tularensis* from a clinical specimen,
— demonstration of a specific antibody response.

For probable cases:
— a single high titre,
— detection of *F. tularensis* in a clinical specimen by fluorescent assay.

Case classification

Possible:	N.A.
Probable:	a clinically compatible case that fulfils the laboratory criteria for a probable case or has an epidemiological link.
Confirmed:	a clinically compatible case that is laboratory confirmed.'