STATUTORY INSTRUMENTS

2002 No. 1281

The Security of Pathogens and Toxins (Exceptions to Dangerous Substances) Regulations 2002

2.—(1) Where any of the conditions or group of conditions set out in paragraphs (2) to (5) is satisfied, something which would otherwise fall within section 58(4)(a) of the Act is not to be regarded as a dangerous substance.

(2) In the case of a pathogen or toxin, those conditions are:

(a) that it exists in the form of, or is included in, a medicinal product; or

(b) that it is an immunological product intended to diagnose whether a state of immunity to certain diseases exists in human beings or animals.

(3) In the case of a pathogen, those conditions are:

(a) that it is modified for use to be administered to one or more human beings or animals for a medicinal purpose; or

(b) that it is kept in such a way that it is no longer in a state that will allow it to be propagated; or

(c) that it is kept—

(i) as part of a clinical specimen for diagnostic purposes, and

(ii) for no longer than is reasonably practicable for its disposal after the time when the diagnosis has been made.

(4) In the case of a toxin which is neither a botulinum toxin nor a clostridium perfringens toxin (other than clostridium perfringens alphatoxin), those conditions are:

(a) that, in the case of premises which are not divided into secure parts, the amount of the toxin in question kept at any particular premises does not exceed 5 milligrams (whether or not the amount of that toxin taken together with any other toxin at those premises exceeds that amount); or

(b) that the amount of the toxin in question kept at any particular secure part of any premises does not exceed 5 milligrams (whether or not the amount of that toxin taken together with either—

(i) any other toxin kept at the same secure part, or

(ii) the same or any other toxin kept at another secure part of the premises in question,

exceeds that amount).

(5) In the case of any toxin, those conditions are:

(a) that it exists only as an immunotoxin; or

(b) that it has not been deliberately isolated or extracted from its natural source.

(6) In this regulation:

"administer" has the same meaning as in section 130(9) of the Medicines Act 1968(**1**);

(**1**) 1968 c. 67; section 130(9) was amended by paragraph 3(10) of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40).

"immunotoxin" means a conjugate of one cell specific monoclonal antibody and a toxin or subunit of a toxin, that selectively affects diseased cells;

"medicinal product" means any substance or article which is held in a form which is ready to be administered to one or more human beings or animals for a medicinal purpose;

"medicinal purpose" has the same meaning as in section 130(2) of the Medicines Act 1968; and

"secure part", in relation to premises, means a part of the premises which is securely divided from any other part of the premises at which a toxin is kept.