

Foreword to the guidance documents relating to micro-organisms

The OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology decided at its first session, in June 1995, to focus its work on the development of *consensus documents* which are mutually acceptable among Member countries. These consensus documents contain information for use during the regulatory assessment of a particular product.

On reviewing a published consensus document and drafting other consensus documents on micro-organisms, the Working Group felt that these documents did not focus in a straightforward way on questions that are relevant to risk/safety assessment issues.

Responding to the concern, the Working Group decided to take an alternative approach, namely the development of *guidance documents*, in the micro-organisms area. Guidance documents are intended to provide guidance on specific topics and issues that are relevant to risk/safety assessment in biotechnology. The Working Group also established a sub-working group that consists of experts on micro-organisms and focuses on projects related to the environmental applications involving micro-organisms, especially bacteria. Subsequently, the sub-working group has developed several documents useful for environmental risk/safety of micro-organisms.

The three Guidance documents currently available on Taxonomy (2003); Detection techniques (2004); and Horizontal gene transfer between bacteria (2010), are reproduced below.



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