Presentation -1

BIOSAFETY HISTORY

Biosafety History

Discussions on the possible hazards of cloning recombinant DNA molecules began in the early 1970s.

The main concerns focussed on

(1) laboratory practices needed to handle serious human and animal pathogens,

(2) possibility of creation of 'hybrid organisms' with biological activities of an unpredictable nature, and

(3) the escape of 'hybrid organisms' from the laboratory with unpredictable consequences.

These concerns were examined by a committee of National Academy of Sciences (U.S.A.) in 1974.

In February 1975, a historic international meeting was convened at Asilomar, California

The conclusions from the conference were as follows:

(i) certain experiments should be deferred,

(ii) most of the work on recombinant DNA could proceed with appropriate safety measures,

(iii) potential risks were assigned to different types of experiments, and

(iv) such safe bacteria and plasmids that could not survive in the environment if they escaped from the laboratory should be developed.

The first NIH guidelines were prepared in 1975

The guidelines were revised after two years; and were made much less restrictive.

By 1981, most cloning experiments in E. coli K-12, certain strains of *Bacillus subtilis* and *Saccharomyces cerevisiae* were considered exempt from other requirements of NIH guidelines.

A major revision of the guidelines was effected in 1982; containment levels were lowered

Defintions of Some Modern Biotechnology Terms

Modern biotechnology *means the application of in vitro nucleic acid techniques, including recombinant DNA techniques and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family that overcomes natural physiological, reproductive or recombination barriers and that are not the techniques of traditional breeding and selection.*

Contained use *means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with and their impact on, the external environment.*

Deliberate introduction and 'field testing' are often used as synonyms of planned introduction.

Recombinant DNA molecules are defined as either.

i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to yield DNA molecules that can replicate in a living cell, or

ii) molecules that result from replication of the molecules described in (i) above.

Objectives of Safety Guidelines

The National Institute of Health (NIH, USA) -Guidelines for recombinant DNA research with a view to specify the practices for constructing and handling

(i) recombinant DNA molecules, and

(ii) organisms and viruses containing recombinant DNA molecules.

These guidelines require approval and clearance of any recombinant DNA experiment that requires such approval/clearance from NIH or another Federal agency.

All experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA- derived from recombinant DNA into human subjects can not be initiated without submission of the required information to NIH and other specified agencies.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity has been designed to cover

- ✓ the transboundary movement, trails it, handling and
- ✓use of all living modified organisms that may have adverse effects on the conservation and
- ✓sustainable use of biological diversity, taking into account risks to human health.

THANK YOU

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