

40 C.F.R. § 725.421

Introduced genetic material.

For a new microorganism to qualify for either exemption under this subpart, introduced genetic material must meet all of the criteria listed in this section.

(a) *Limited in size.* The introduced genetic material must consist only of the following:

- (1) The structural gene(s) of interest.
- (2) The regulatory sequences permitting the expression of solely the gene(s) of interest.
- (3) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.
- (4) The nucleotide sequences needed for vector transfer.
- (5) The nucleotide sequences needed for vector maintenance.

(b) *Well-characterized.* For introduced genetic material, well-characterized means that the following have been determined:

- (1) The function of all of the products expressed from the structural gene(s).
- (2) The function of sequences that participate in the regulation of expression of the structural gene(s).
- (3) The presence or absence of associated nucleotide sequences and their associated functions, where associated nucleotide sequences are those sequences needed to move genetic material including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(c) *Poorly mobilizable.* The ability of the introduced genetic material to be transferred and mobilized is inactivated, with a resulting frequency of transfer of less than 10⁻⁸ transfer events per recipient.

(d) *Free of certain sequences.* (1) The introduced genetic material must not contain a functional portion of any of the toxin-encoding sequences described in this paragraph (d).

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