[0032]

The promoter for use in the method for producing a foreign gene-derived protein according to the present invention may be a mutant polynucleotide consisting of a nucleotide sequence comprising a deletion, substitution, and/or addition of one or more, preferably 1 to 300, more preferably 1 to 30 nucleotides in any one nucleotide sequence selected from the group consisting of the nucleotide sequences shown in SEQ ID NOs: 1 to 9, and having promoter activity.

[0033]

The introduction of a mutation (deletion, substitution, and/or addition) into the nucleotide sequence can be performed by an approach known in the art such as the Kunkel method or the gapped duplex method, or a method equivalent thereto. For example, a kit for mutation introduction which exploits site-directed mutagenesis (e.g., Mutant-K (manufactured by Takara Bio Inc.) or Mutant-G (manufactured by Takara Bio Inc.)), or LA PCR *in vitro* Mutagenesis series kit from Takara Bio Inc. can be utilized. Such a mutant polynucleotide can also be used as the promoter of the present invention.

[0034]

The foreign gene expression-enhancing activity possessed by the promoter of the present invention can be examined by using, as an indicator, the activity of a protein encoded by a reporter gene, such as firefly luciferase, or the amount of an antibody produced in fed-batch culture. When the amount of the antibody produced in fed-batch culture is equivalent or higher, preferably 1.2 or more times, more preferably 1.5 or more times higher by use of the promoter of the present invention compared with use of a human EF-1α promoter, it can be determined that this promoter has foreign gene expression-enhancing activity. Even in cases where the amount of an antibody produced in fed-batch culture is increased by approximately 1.2-fold or more, a reduction of cell culture scale,

For combined use with the promoter of the present invention, any one of the DNA elements described above may be used alone, or two or more copies of one DNA element may be used. Alternatively, two or more DNA elements may be used in combination.

[0044]

The DNA element used in the present invention may consist of a nucleotide sequence having 80% or higher, preferably 90% or higher, more preferably 95% or higher, most preferably 99% or higher identity to the nucleotide sequence shown in any of SEQ ID NOs: 35 to 37, and having foreign gene expression-enhancing activity. A homology search of the nucleotide sequence can be performed using, for example, a program such as FASTA or BLAST and the DNA Databank of JAPAN as the subject of the search.

[0045]

A person skilled in the art can readily obtain such a homolog gene of the DNA element of the present invention with reference to Molecular Cloning (Sambrook, J. et al., Molecular Cloning: a Laboratory Manual 2nd ed., Cold Spring Harbor Laboratory Press, 10 Skyline Drive Plainview, NY (1989)), etc. Likewise, the identity of the nucleotide sequence described above can be determined by FASTA search or BLAST search.

[0046]

The introduction of a mutation (deletion, substitution, and/or addition) into the polynucleotide can be performed by an approach known in the art such as the Kunkel method or the gapped duplex method, or a method equivalent thereto. For example, a kit for mutation introduction (e.g., Mutant-K (manufactured by Takara Bio Inc.) or Mutant-G (manufactured by Takara Bio Inc.), or LA PCR *in vitro* Mutagenesis series kit from Takara Bio Inc. can be utilized which exploits site-directed mutagenesis. Such a mutant polynucleotide can also be used as the DNA element of the present invention.