

What should we do if we manufacture an active substance that does not use a fermentation process but does use a material of fish origin?



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Answer:

In your CEP application, you should include a discussion on the potential presence of histamine and the resulting control strategy for its contamination of the active substance. Histamine is known to be a potential contaminant in processes where material of fish origin is used.

A separate FAQ is available for substances manufactured using a fermentation process.