General Specifications and Considerations for Enzyme Preparations used in Food Processing

The following general specifications prepared at the 57th JECFA (2001) and published in FNP 52 (Addendum 9), superseded specifications prepared at the 35th JECFA (1989) and published in FNP 49 (1990) and in FNP 52 (1992); the general specifications prepared at the 25th JECFA (1981) and published in FNP 19 (1981) and FNP 31/2 (1984); amendments at the 51st JECFA published in FNP 52 Add 6 (1998); amendments at the 53rd JECFA (1999) and partially published in FNP 52 Add 7 (1999).

Enzyme Nomenclature

Recommendations of the Nomenclature Committee of the International Union of Biochemistry, Academic Press (1992) with later supplements: Enzyme preparations used in food processing are usually named according to the substrate to which the enzyme is applied, such as protease or amylase. Some traditional names are also in use, such as malt, pepsin and rennet.

Definition

Enzyme preparations consist of biologically active proteins, at times combined with metals, carbohydrates and/or lipids. They are obtained from animal, plant or microbial sources and may consist of whole cells, parts of cells, or cell free extracts of the source used. They may contain one or more active components as well as carriers, solvents, preservatives, antioxidants and other substances consistent with good manufacturing practice. They may be liquid, semi liquid, dry or in an immobilized form (immobilized enzyme preparations are preparations which have been made insoluble in their intended food matrix by physical and/or chemical means). Their colour may vary from virtually colourless to dark brown.

Active components

The principal activities are characterized by their systematic names and Enzyme Commission Numbers.

The activities of enzyme preparations are measured according to the reaction catalyzed by individual enzymes and are usually expressed in activity units per weight of preparation.

Source materials

Animal tissues used for the preparation of enzymes must comply with meat inspection requirements and be handled in accordance with good hygienic practice.

Plant material used in the production of enzyme preparations must consist of components that leave no residues harmful to health in the processed finished food under normal conditions of use.

Microbial sources used in the production of enzyme preparations may be native strains or variants of microorganisms, or be derived from native strains or variants by the processes of selective serial culture or genetic modification. Production strains for food enzyme preparations must be nonpathogenic and nontoxigenic. The evaluation of enzyme preparations from fungal sources for toxigenicity shall include a determination that they do not contain toxicologically significant amounts of mycotoxins that are known to be synthesised by strains of the production microorganism's species or of species related to the production microorganism. Source microorganisms must be discrete and stable strains or variants that have been taxonomically characterised to enable them to be assigned unique identities as the sources of the enzyme preparations that are the subject of individual specifications. The reference or production strain number may be included in individual specifications. The production strains must be maintained under conditions that ensure the absence of strain drift and, when used in the production of enzyme preparations, must be subjected to methods and culture conditions that are applied consistently and reproducibly from batch to batch. Such conditions must ensure the absence of toxin production by the source organism and prevent the introduction of microorganisms that could be the source of toxic materials and other undesirable substances. Culture media used for the growth of microbial sources must consist of components that leave no residues harmful to health in the processed finished food under normal conditions of use.

Enzyme preparations are produced in accordance with good food manufacturing practice. They cause no increase in the total microbial count in the treated food, over the level considered to be acceptable for the respective food.

Carriers and other additives and ingredients

The carriers, diluents, excipients, supports and other additives and ingredients (including processing aids) used in the production, distribution and application of enzyme preparations must be substances that are acceptable for the relevant food uses of the enzyme preparations concerned, or substances which are insoluble in food and removed from the food material after processing.

In the case of immobilized enzyme preparations, leakage of carriers, immobilization agents and active enzymes must be kept within acceptable limits as specified in the individual specifications.

In order to distinguish the proportion of the enzyme preparation derived from the source material from that contributed by diluents and other additives and ingredients, individual specifications may require a statement of percentage Total Organic Solids (T.O.S.) which is defined as follows:

% T.O.S. = 100 (A + W + D)

Where

A = % ash, W = % water and D = % diluents and/or other additives and ingredients.

Purity

Lead

Not more than 5 mg/kg.

Determine using atomic absorption technique appropriate to the specified level. The selection of the sample size and the method of sample preparation may be based on the principles described in Volume 4.

Microbiological criteria

Salmonella spp.: Absent in 25 g sample.

Total coliforms: Not more than 30 per g.

Escherichia coli: Absent in 25 g sample

Determine using procedures described in Volume 4.

Antibiotic activity

Absent in preparations from microbial sources.

Other considerations

An overall safety assessment of each enzyme preparation intended for use in food or food processing must be performed. This assessment should include an evaluation of the safety of the production organism, the enzyme component, side activities, the manufacturing process, and the consideration of dietary exposure. Guidelines for safety assessments of food enzyme preparations derived from microbial strains have been developed (Pariza and Foster, 1983; Pariza and Johnson, 2001; IFBC, 1990; Scientific Committee for Foods, 27th series). Further, several internationally recognized scientists and expert groups have prepared guidelines for the safety assessment of food and food ingredients developed through biotechnology (OECD, 1993: Health Canada, 1994; FAO/WHO, 1996; and Jonas et al., 1996) which are applicable to enzyme preparations derived from recombinant sources. The following points need emphasis when considering the production of enzyme preparations from genetically modified microorganisms:

1. The genetic material introduced into and remaining in the production microorganism should be characterized and evaluated for function and safety. It should be demonstrated that no unexpected genetic material was introduced into the host microorganism, e.g., by providing the sequences of the final introduced genetic material and/or molecular analysis of the introduced sequences in the final production strain. This would include demonstration that the genetic material does not contain genes coding for virulence factors, protein toxins, or enzymes that may be involved in the synthesis of mycotoxins or any other toxic or undesirable substances.

2. If the production microorganism is capable of producing proteins that inactivate clinically useful antibiotics, documentation should be provided that the finished enzyme preparation contains neither antibiotic inactivating proteins at concentrations that would interfere with antibiotic treatment nor DNA that is capable of transforming microorganisms, which potentially could lead to the spread of antibiotic resistance.

3. The need to evaluate the allergenic potential of the potential gene products encoded by the DNA inserted in the production microorganism should be considered (see FAO/WHO, 2000 and 2001).

References

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