

CODEX GENERAL GUIDELINES FOR THE UTILIZATION OF VEGETABLE PROTEIN PRODUCTS (VPP) IN FOODS

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1. PURPOSE

To provide guidance for the safe and suitable use of vegetable protein products (VPP) in foods by establishing:

- (i) principles to ensure that the nutritional quality of the food containing VPP is appropriate to their intended use; and
- (ii) principles for the appropriate labelling of foods containing VPP.

2. SCOPE

These general guidelines are intended to apply to all situations in which proteins derived from vegetable sources other than Single Cell Protein are utilized in foods.

3. DEFINITIONS

Available Amino Acids: Amino Acids from food proteins that are absorbed and are available for metabolism.

Amino Acid Score (formerly chemical score): (mg of the limiting amino acid in 1.0 g of test protein)/(mg of the same amino acid in 1.0 g of protein as defined by the reference amino acid pattern).

Bioavailability: the extent to which an amino acid or other essential nutrient is absorbed and available for metabolism.

Complementation (of proteins): the increase in protein nutritional value achieved by mixing two proteins, which have different limiting amino acids, in those proportions which result in the protein quality of the mixture being higher than that of either of the component protein occurs when the first protein has an excess of the amino acid which is limiting in the second protein and *vice versa*.

Limiting amino acid: the essential amino acid of a food protein present in the lowest proportion relative to the amount of that amino acid in the Reference Amino Acid Pattern.

Net Protein Ratio (NPR): (weight gain of test group of rats plus weight loss of non-protein group)/(protein consumed by test group).

Nutritional Adequacy: See Section 7.2

Protein Quality: The extent to which a protein source provides essential amino acids and indispensable nitrogen for meeting human requirements. Protein quality is primarily determined by the level, distribution and bioavailability of the essential amino acids in a protein source.

Reference Amino Acid Pattern: the levels and distributions of essential amino acids of an ideal protein specified by FAO/WHO/UNU (1985) for meeting the requirements of the 2-5 year old child when consumed at the level of safe protein intake.

Relative NPR (RNPR): NPR expressed relative to a standard protein.

Supplementation (in protein nutrition): the increase in protein quality achieved by the addition of a moderate amount of a protein having a high content of an essential amino acid to another protein in which that amino acid is limiting.

Utilizable Protein: Protein which is metabolically available for meeting human requirements for essential amino acids and indispensable nitrogen. Calculated as the product of crude protein in 100 grams of product ($N \times 6.25$) \times protein quality expressed as a fraction (maximum protein quality = 1.0).

Vegetable Protein Products (VPP): VPP are food products produced by the reduction or removal from vegetable materials of certain of the major non-protein constituents (water, oil, starch, other carbohydrates) in a manner to achieve a protein ($N \times 6.25$) content of 40% or more. The protein content is calculated on a dry weight basis excluding added vitamins, minerals, amino acids and food additives.

4. BASIC PRINCIPLES

4.1 VPP intended for human consumption should not represent a hazard to health. The annex to these guidelines, which is based on revised PAG/UNU Guideline No. 6, should be consulted for testing the safety and nutritional quality of VPP.

4.2 The nutritional quality of the VPP should be appropriate for its intended use.

4.3 The presence of VPP in foods should be clearly indicated on the label.

In this connection foods containing vegetable protein products should be labelled in accordance with the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985, Rev. 1-1991, Codex Alimentarius Volume 1A), with the proviso that:

- (a) A complete list of ingredients should be declared on the label in descending order of proportion except that, in the case of added vitamins and minerals, these should be arranged as separate groups and in these groups the vitamins and minerals need not be listed in descending order of proportion.
- (b) The ingredient statement should contain the source (e.g., pea, groundnut), and where

appropriate product type and processed form (e.g. textured, spun) of each vegetable protein ingredient in the food product.

- (c) Any nutrient labelling should be in accordance with the Codex Guidelines on Nutrition Labelling.

5. USES OF VPP FOR FUNCTIONAL AND OPTIONAL PURPOSES

5.1 When VPP are used at low relative levels for functional purposes, or as optional ingredients, their use should not result in any replacement of principal protein and associated nutrients in the food to which they are added.

5.2 For the purpose of defining VPP as a functional or optional ingredient in Codex Standards the level of VPP should be calculated on a dry weight basis in the final product. The actual level of use will vary according to the nature of the protein and of the product concerned.

5.3 The use of VPP as a functional or optional ingredient should be regulated in the same way as other functional or optional ingredients with no required change in the name of the product. However, a declaration of the presence of VPP should be given in connection with the name of the product if its omission would mislead the consumer.

6. USES OF VPP TO INCREASE CONTENT OF UTILIZABLE PROTEIN

6.1 VPP may be used to improve the protein nutriture of populations by increasing the content of utilizable protein in the diet. This can be done by increasing the protein content of the diet or increasing the protein quality of the proteins in the diet, or a combination of both. It should be noted that increasing the protein quantity and/or quality of a diet will be ineffective if energy requirements are not met.

6.2 In general, the minimum aim of supplementation and/or complementation should be to increase utilizable protein by 20%.

6.3 For a significant degree of complementation in protein quality of diets deficient in lysine or in methionine + cysteine or in tryptophan, the complementary protein should contain at least 5.8% available lysine or 2.5% available methionine + cysteine or 1.1% available tryptophan, respectively.

6.4 Addition of amino acids should only be considered when the desired increase in utilizable protein cannot practicably be achieved by a suitable mixture of complementary or supplementary proteins. Only L forms of amino acids should be used.

6.5 Since a variety of VPP are available for use for this purpose, the choice of VPP should favour products which have been processed in such ways and to such extent as to optimize both the nutritional contributions and economic considerations.

6.6 The addition of vitamins and minerals should be in accordance with the Codex General Principles for the Addition of Essential Nutrients to Foods.

6.6.1 The need for fortification of VPP with vitamins and minerals should be considered in the following instances:

- (i) when the VPP is a suitable vehicle for fortification in regions where there is a demonstrated need for increasing the intake of one or more vitamin(s) or mineral(s) in one or more population groups;
- (ii) when the VPP contains anti-nutritional factors (e.g., phytate) which may interfere with the bioavailability or utilization of nutrients.

6.6.2 The need for nutritional adequacy of the VPP should be considered in those instances in which the VPP replaces staple ingredients which are higher in vitamins and minerals than the VPP.

6.7 When VPP is used in a food to increase the content of utilizable protein, its presence need not be indicated in the name of the food unless its omission would mislead the consumer.

6.8 The protein content of a food in which VPP has been added to increase the content of utilizable protein should be declared in accordance with the Codex Guidelines on Nutrition Labelling. Where claims are made with respect to the protein quality of the food, the protein nutritional value should be assessed according to the established methods for protein quality measurement.

7. USES OF VPP IN PARTIAL OR COMPLETE SUBSTITUTION OF THE ANIMAL PROTEIN IN FOODS

7.1 The use of VPP to substitute partially or completely for animal protein in foods should be permitted provided that the presence of VPP is clearly indicated on the label. Where the completely or partially substituted food is intended to replace a food which has been identified as a significant source of energy and/or essential nutrients in the food supply, consideration should be given to the nutritional adequacy of the partially or completely substituted food. Where there is demonstrated evidence of public health need, nutritional adequacy should be required.

7.2 The nutritional adequacy of a product can be defined in terms of protein quality and quantity and content of minerals and vitamins.

Such a product should be considered nutritionally equivalent if:

- (i) its protein quality is not less than that of the original product or is equivalent to that of casein and
- (ii) it contains the equivalent quantity of protein (N x 6.25) and those vitamins and minerals which are present in significant amounts in the original animal products.

7.3 The nutritional adequacy of a partially substituted animal product can be achieved by any of the following three methods:

- (a) By using a VPP which is nutritionally equivalent in terms of protein quantity and quality and levels of vitamins and minerals, or
- (b) By using a VPP equivalent which is nutritionally adequate with respect to levels of vitamins and minerals, but placing the requirements for protein quantity and quality on the final product, or
- (c) By the addition of the required nutrients to the partially substituted product (i.e., by placing all nutritional requirements on the partially substituted product).

The second approach is considered the most satisfactory because:

- (i) The first method does not make allowance for the complementary effect of animal-VPP mixtures on protein quality. For example, according to its amino acid score, wheat gluten (which would require the addition of several amino acids before it could meet the protein quality requirement for partial substitution) could be used to substitute meat protein up to 30% without any significant deleterious effect on adequacy of the final product in protein quality.
- (ii) The third method would require that the vitamin and mineral content of the animal portion of the partially substituted product be known and accounted for in each instance. Moreover, the expertise and control facilities for ensuring proper addition of nutrients and stability of vitamins may not exist in places where VPP would be utilized in animal products such as retail outlets and meat packing plants.

7.4 In the case of completely substituted (simulated) animal products, all the nutritional adequacy requirements (i.e. protein quantity and quality as well as vitamins and minerals) should be placed on the final product.

7.5 When VPP partially substitutes for the protein of an animal product, the following nomenclature criteria should apply:

- (i) The presence of the VPP should be indicated in the name of the food.
- (ii) The name of the substituted product should describe the true nature of the product; it should not mislead the consumer; and it should enable the substituted product to be distinguished from products with which it could be confused.
- (iii) In cases where the substitution results in an amount of the animal protein product lower than that required by a Codex or national standard, the name of the standardized animal food should not be used as part of the name of the substituted product unless properly qualified.
- (iv) The provisions of a Codex Standard or a national compositional standard should be taken into full account when determining the name of the food.

7.6 In the case of a simulated animal product in which 100% of the protein is from VPP, the established or common name of the food should be the name of the VPP with appropriate flavour designation or other descriptive phrasing.

8. USES OF VPP AS SOLE PROTEIN SOURCE IN PRODUCTS WITH NEW IDENTITIES

There is an expanding group of foods made with VPP that are not intended to supplement utilizable protein or to replace traditional protein foods. Each of these foods will develop an identity of its own and will have its own nutrient composition. There need not be specific nutrient requirements for these foods. As with any other foods, these VPP foods should be safe, should be produced in accordance with Good Manufacturing Practices and should be labelled in accordance with the Codex Standard for the Labelling of Prepackaged Foods.

ANNEX

**CODEX GUIDELINES FOR TESTING SAFETY AND NUTRITIONAL QUALITY OF
VEGETABLE PROTEIN PRODUCTS¹**

Vegetable Protein Products (VPP) are vegetable products which have been processed in a manner which results in a significant degree of increase in the protein content in the final product. VPP have found significant uses as functional ingredients in food products and as protein extenders and replacements. Certain VPP, particularly those derived from soya beans, have been subjected to intensive investigation. From these investigations has come an appreciation of the technological properties which may be significant to the food use of VPP. As new sources of VPP are developed guidance is necessary on how these products should be tested for safety and nutritional quality.

The raw materials from which VPP are produced may contain naturally occurring toxic or anti-nutritional factors, e.g. glucosinolates in Brassica spp, gossypol in cottonseed, hemagglutins and trypsin inhibitors in legumes. Some of these factors may still be present in the VPP after processing. The processing involved in the preparation of VPP such as treatment with heat, organic solvents, acids, alkalis, salts and enzymes, etc. tends to increase the level of certain nutrients such as sodium and eliminate others such as vitamins. It may also result in changes in digestibility, absorption and protein quality. Furthermore, residual solvents or reaction products may be present in the VPP.

In the light of the above observations, it becomes important that prior to the use as human food, VPP be subjected to adequate testing to demonstrate safety and appropriate nutritional quality. In order to aid food manufacturers in determining what testing is required to evaluate safety and nutritional value of VPP, the Codex Committee on Vegetable Proteins (CCVP) has developed this guideline.

The purpose of this guideline is not to lay down a rigid plan or to cover all procedural details but to serve as a general recommendation for the testing of vegetable protein products. A distinct VPP needs to be tested pursuant to this guideline only once, that is, to obtain a toxicological and nutritional profile for the VPP. The guideline is not intended for use in production quality control testing on a lot-by-lot basis. Novel VPP, those processed by new techniques from commonly used sources and those produced from sources not previously used as human food, require thorough testing. VPP which are produced by minor processing variants from sources commonly used as food need not be tested so thoroughly. Prior history of safe use may be taken into account in evaluation of a novel VPP proposed for general consumption, but this alone is not necessarily sufficient to preclude adequate pre-clinical testing by currently available, more objective, laboratory animal feeding studies, and, where applicable, studies using human volunteers. Adequacy of history of safe use will have to be evaluated on a case-by-case basis. Applicable data in the available literature may be used in lieu of separate testing pursuant to this guideline. The content and depth of the investigations for a specific VPP will depend on the kind of process applied in its preparation, and the conditions of its intended use as prepared for consumption and the presence of known toxic or anti-nutritional factor(s) in the starting material.

¹ Modified version of the UNU/PAG Guideline No. 6 on preclinical testing of novel sources of food. Food and Nutrition Bulletin Vol. 5 No. 1 (1983).

1. CATEGORIES OF INFORMATION NEEDED

The following information is required for each novel VPP.

1.1 Specifications and Process Details

A general description of the process used to prepare the VPP and the specification of the VPP should be included. This description should be sufficient to enable those evaluating the product to identify potential problem areas, such as processing damage to the nutrient content.

1.2 Nutritional Value

The nutritional value of the VPP should be predicted first from its amino acid content and then by means of (insert reference to method for determining protein quality as described in the applicable Codex standard).

1.3 Microbiological Status

The procedures that are required to maintain adequate sanitation with respect to the sources of raw materials and conditions under which they are processed to produce the VPP should be included.

1.4 Toxicological Safety

The safety of the VPP should be predicted from information concerning methods of production, chemical and physical properties, content of micro-organisms and their metabolites. This should be supported where necessary by safety data using laboratory animals.

2. EVALUATION

Each novel VPP should be subjected to the following analysis using procedures indicated in the Recommended General Standard for VPP unless otherwise specified.

2.1 Chemical

2.1.1 Proximate composition

Moisture, total solids, total nitrogen, crude protein (N x 6.25) fat (ether extract), ash, fibre, total carbohydrates, and indigestible carbohydrates (dietary fibre) (insert reference to the appropriate method).

2.1.1.1 Nitrogenous components

Amino acid composition should be expressed as g amino acid/16gN, and information on the

recovery of amino acid nitrogen should be obtained. The presence and amount of non-protein nitrogenous components, if any, should be determined.

2.1.1.2 **Lipid**

The solvent extract should be analyzed for the fatty acid profile by chromatography if the solvent extract is greater than 1 percent. The solvent extract should also be examined for the presence of unusual (e.g. cyclic) fatty acids.

2.1.1.3 **Mineral elements**

The material should be analyzed for its content of metals or minerals or toxicological or nutritional significance (including arsenic, calcium, cadmium, copper, fluoride, iron, lead, magnesium, manganese, mercury, phosphorous, potassium, selenium, sodium and zinc).

2.1.1.4 **Carbohydrates**

Analysis should be carried out to characterize the available (digestible) carbohydrates.

2.1.1.5 **Vitamins**

Analysis should be conducted for all of the major vitamins except those for which low lipid content or instability under processing conditions indicate little likelihood of their presence in significant amounts.

2.1.2 **Solvent residues**

The product should be examined for the presence of potentially hazardous solvent residues.

2.2 **Microbial**

The VPP should be examined to determine numbers and types of micro-organisms to be expected under sanitary conditions of production or processing and to establish its freedom from microbial toxins and toxigenic organisms.

2.3 **Nutritional**

Nutritive value of VPP should be assessed by (insert reference to method for protein quality described in appropriate Codex Standard).

2.4 **Toxicological**

2.4.1 **Subacute toxicity studies**

The purpose of these studies is to delineate the toxic potential of VPP and to elucidate such problems as species sensitivity, the nature of gross and micro-pathological changes and the approximate dose level at which these effects occur. They also provide guidance for the selection of dosage for chronic toxicity tests and any functional or biochemical studies that may be necessary. They should be carried out in accordance with recognized codes of Good Laboratory Practice.

2.4.1.1 **Animals**

At least two species of healthy animals of both sexes, one rodent, preferably rats, and one non-rodent, should be used. Among the non-rodent species, beagle dogs, monkeys, and miniature pigs may be considered. If biochemical information is available that indicates the species of animals most likely to elicit information simulating man, such species should be selected for these studies. Rodents are usually started on tests at or shortly after weaning and are assigned to groups of equal size balanced with respect to litter distribution, sex and average weight. Groups should be large enough to provide statistically adequate data.

2.4.1.2 **Diet**

The diet should be nutritionally adequate for all test groups. If the test product has been shown to be nutritionally complete, it may be fed as a replacement for basic protein in the diet. Particular attention should be paid to balancing the tests and control diets in respect to minor nutrients. It is not feasible to test a VPP at large multiples of the potential use level. Nevertheless, the highest practicable use level should be included and if feasible, grade levels of the VPP should be reflected in the experimental design. It is not realistic to establish a dose response curve.

2.4.1.3 **Length of study**

Subacute toxicity feeding trials should be of at least three months duration.

2.4.2 **Other studies**

Following an appraisal of the source and the method of manufacture of the VPP together with the results of nutritional and subacute toxicity studies, the need for further studies including chronic, reproduction, teratogenic and mutagenic studies will be evaluated.

2.5 **Statistical**

Reports of investigations must include complete details, data for control as well as test groups and appropriate statistical analysis of the findings.