codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 89/30

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Eighteenth Session
Geneva, 3-14 July 1989

REPORT

OF THE FIFTH SESSION OF THE CODEX COMMITTEE ON VEGETABLE PROTEINS

Ottawa, Canada February 6-10, 1989

Note: This document incorporates Codex Circular Letter 1989/11-VP

CX 5/90.2 CL 1989/11-VP
CX 2/7.2 (18th) March 1989

To : - Codex Contact Points
- Participants at the Fifth Session of the Codex Committee on Vegetable Proteins
- Interested International Organizations

FROM : Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy

SUBJECT : Distribution of the Report of the Fifth Session of the Codex Committee on Vegetable Proteins (ALINORM 89/30)

PART A : MATTERS OF INTEREST TO THE 18TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

1. Draft Guidelines and Standards at Step 8 of the Procedure

The following guidelines and standards have been submitted for adoption to the 18th Session of the Commission at Step 8 of the Procedure.

Draft Guidelines for the Utilization of Vegetable Protein Products in Foods (Para 53, Appendix II)

Draft Standard for Vegetable Protein Products (Para 85, Appendix III)

Draft Standard for Soy Protein Products (Para 98, Appendix IV)

Governments wishing to propose amendments to the above draft guidelines and standards should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (See 6th Ed. of the Procedural Manual of the Codex Alimentarius Commission),

Comments should be sent to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy not later than 15 April 1989,

SUMMARY AND CONCLUSIONS

The Fifth Session of the Codex Committee on Vegetable Proteins reached the following conclusions during its deliberations:

- Agreed to bring the report respecting vegetable protein production and utilization for human use to the attention of the Commission (para 13).

- Agreed that the protein digestibility corrected amino acid score method was the best available for routine evaluation of protein quality of vegetable protein products. However, because the methodology used to measure protein quality had broad implications beyond the purview of the CCVP, it recognized the need for the wider scientific community to address issues such as amino acid methodology, protein digestibility, amino acid bioavailability, and correlations in humans and accordingly recommended that a Joint FAO/WHO expert consultation should be held in order to review the method (Para 20).

- Agreed that the processing aids that could be used in the manufacture of primary forms of vegetable protein products and soya protein products should be restricted to those contained in the advisory inventory of the CAC (Para 29).

- Agreed that at the present time of development the enzyme immuno essays would provide the best approach for effective differentiation of vegetable and animal proteins (Para 35).

- Advanced the General Guidelines for the Utilization of Vegetable Protein Products in Foods to Step 8 (Para 53).

- Agreed not to establish maximum levels for contaminants in VPP and SPP on the basis of the meager information available to it and agreed to include a general statement in the standards that emphasized the desirability of minimizing heavy metal contamination (Para 58).

- Recommended that limits for trypsin inhibitor activity not to be set for soy protein products, but if limits were needed they should be defined in terms of the finished product (Para 63).

- Advanced the Draft Standard for vegetable Protein Products to Step 8 (Para 85).

- Advanced the Draft Standard for Soya Protein Products to Step 8 (Para 98).

- Having concluded its current business agreed to adjourn sine die (Para 107)

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INTRODUCTION

1. The Fifth Session of the Codex Committee on Vegetable Proteins (CCVP) was held in Ottawa, from 6-10 February, 1989 through the courtesy of the Government of Canada; 40 representatives and observers from 14 countries and 1 International organization were present. The session was chaired by Dr. Norman Tape, Director, Food Research Centre, Agriculture Canada. The list of participants is given in Appendix I to this report.

OPENING OF THE SESSION (Agenda Item 1)

2. The session was formally opened by Mr. John L. Paynter, Assistant Deputy Minister, Economic and Trade Policy Branch, Department of External Affairs, Canada.

3. Mr. Paynter, in opening the session, stated that the Codex Alimentarius Commission (CAC) had proven its credibility in developing a series of food regulations and provided an active forum for elaborating international standards for commodities moving in international trade. International food standards were a necessity to stop dampening dynamic growth in trade by using regulations as non-tariff barriers. International cooperation from all angles is needed more than ever to elaborate food standards that would be agreeable to all countries. He noted that the GATT, together with Codex, can be effective in facilitating trade, particularly when their efforts are combined. Indeed, the advancement of free trade for agricultural products is one of the key goals of the current Uruguay round of multilateral trade negotiations. The work on health and sanitary measures in the GATT is only starting to get underway. Freer trade would be greatly facilitated through efforts to link the GATT and the Codex and other organizations interested in food standardization work. He proposed that the industry in each country takes an active role in the development of food standards and appealed to the governments to work with industry to accomplish well defined and useful standards.

IN MEMORIUM: DR. D.L. HOUSTON. DR. ANNE BRINCKER, DR. R.W. WEIK AND DR. C.E. BODWELL

4. The Committee recalled, with sincere appreciation, the contributions made to its work and to the work of the Codex Alimentarius Commission by the late Dr. D.L. Houston, National Codex Coordinator for the U.S.A. and former Administrator, Food Safety Inspection Service, USDA; Dr. Anne Brincker, Chairman of the Codex Committee on Processed Meat and Poultry Products for a number of years and vice-chairman of the Commission; Dr. C.E. Bodwell, delegate to earlier sessions of this committee from U.S.A. and Dr. R.W. Weik who was delegate from U.S.A. to a number of Codex committees, all of whom passed away since the Committee's last session. The Committee observed a minute of silence in their memory.

ADOPTION OF AGENDA (Agenda Item 2)

5. The Committee had before it the provisional agenda of the session as set out in document CX/VP 89/1. The Committee agreed to consider Agenda item 14 immediately after Agenda item 8.

MATTERS OF INTEREST ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 3)

6. The Committee had before it document CX/VP 89/2 containing matters of interest to it arising from Codex Alimentarius Commission and other Codex Committees. The Committee noted that there were a number of matters which would be discussed under other agenda items and agreed to defer discussion on them until the particular agenda

item was presented.

REGULAR REVIEWS OF FOOD ADDITIVE PROVISIONS IN CODEX STANDARDS

7. The Committee noted that the Codex Committee on Food Additives and Contaminants (CCFAC) had agreed to discuss the future activities of the CCFAC in regard to the establishment and regular review of provisions relating to food additives in Codex Standards and the possible mechanism for establishment of general provisions for the use of additives in non-standardized foods as a general approach in the light of changing requirements in international trade.

CONSIDERATION OF PROCESSING AIDS

8. The Committee noted that CCFAC was preparing an inventory of Processing Aids, which catalogued all such substances that might be used in food as processing aids. The inventory is not intended to be a complete and positive list of processing aids.

REPORT OF THE WORKING GROUP RESPECTING VEGETABLE PROTEIN PRODUCTION AND UTILIZATION FOR HUMAN USE (Agenda Item 4)

9. The Committee recalled the discussion at its 4th session on the subject, during which it agreed that an updated version of the document would be useful for information and reference purposes and requested the rapporteur country (U.S.A.) to undertake this task.

10. The Committee had before it an updated version of document CX/VP 89/3, prepared by Dr. Walter J. Wolf (U.S.A).

11. Introducing the document, Dr. Wolf informed the Committee that the present document contained additional information on i) wheat gluten, ii) Single Cell Protein iii) wheat proteins and iv) legume proteins in section (II) on Status of Major Vegetable Protein Sources. A new section (III) dealing with Production, Market Potential and Trends was included and the Regulatory Provisions and Practices for the use of vegetable proteins in foods in 27 countries were updated, based on information provided by EUVEPRO.

12. The Committee noted that the document would need constant updating because of the very dynamic trends in the utilization of vegetable proteins in foods. The delegations of the Netherlands, Switzerland, France and United Kingdom provided some updated information relevant to their countries and it was agreed that this information should be incorporated in the document CX/VP 89/3, and made available to all the member governments and international organizations interested in the subject.

13. The Committee expressed its appreciation to Dr. Wolf for his excellent paper and agreed to bring it to the attention of the Commission.

REPORT OF THE WORKING GROUP ON PROTEIN QUALITY MEASUREMENT (Agenda Item 5)

15. At the 4th Session of CCVP, the Committee concluded that amino acid scoring procedures, including corrections for true digestibility of protein and/or bioavailability of limiting amino acids was the most suitable approach for evaluating protein quality of Vegetable Protein Products. However, any official recommendation on methods for evaluating protein quality of VPP was deferred at the session because i) There was a need to standardize in vitro methods for predicting protein digestibility of foods to be used for correcting amino acid scores and ii) Further improvement in amino acid methodology, especially in determination of tryptophans, was desired.

15. Collaborative studies were undertaken in 1987 and 1988 to address the above issues. These studies revealed that the pH-stat procedure of Pederson and Eggum which was considered to be the most promising in vitro protein digestibility method was not a good predictor of protein digestibility data obtained by the rat balance method which gave results similar to those obtained by the human balance method. Results of the collaborative studies were discussed by the Working Group on Protein Quality Measurement in December 1988 in Beltsville, Maryland. The discussions of the Working Group at that meeting formed the basis of the current report contained in the document CX/VP 89/4, before the Committee.

16. In presenting the report, Dr. Sarwar, (Canada), informed the Committee that the Working Group expressed the view, that amino acid score (based on the amount of the single most limiting amino acid) including corrections for true digestibility of protein (as determined by the rat balance method) be considered as the most suitable routine method for assessing protein quality of most vegetable protein products and other food products. However, additional correction for bioavailability of amino acids might be required in grain legumes and some cereals. The use of the FAO/WHO/UNU (1985) [1] suggested pattern of amino acid requirements (based on the amino acid requirements of a 2-5 year old child) as reference for calculating amino acid scores was endorsed. The development of tables of protein/amino acid digestibility of typical protein sources to facilitate corrections for amino acid scores was anticipated. The need for further research to evaluate and standardize the HPLC methods for amino acid analysis was recognized. The usefulness of the corrected RNPR (CRNPR), as an inexpensive back up procedure for countries which cannot afford to buy and/or maintain the instrumentation needed for amino acid analysis was noted.

[1]. Energy and Protein Requirements: Report of a Joint FAO/WHO/UNU Expert Consultation. Technical Report Series 724, World Health Organization. Geneva, 1985.

17. The Working Group believed that the protein digestibility corrected amino acid scores was the best available method for routine evaluation of protein quality of VPP and other food products. It, however, recognized the need to address specific issues such as amino acid methodology, correlation of results of studies in humans and experimental animals, as well as acceptance of the conclusions of the Working Group by the scientific community. The Working Group, hence, recommended that a conference of protein scientists from university, industry, government and regulatory agencies should be held to facilitate final adoption and implementation of recommended method.

18. The Committee noted the recommendation of the Working Group and agreed to set up a small Working Party to consider the recommendations and to provide advice to the Committee. The Working party had the following terms of reference:

- To propose appropriate follow-up action to the recommendations of the Working Group on Protein Quality.

19. Delegations of the Netherlands, U.S.A., Sweden, U.K. and Canada and the Observer from EUVEPRO participated in the Working Party.

20. The Committee agreed with the report of the Working Party that the protein digestibility-corrected amino acid score method, described in CX/VP 89/4, was the best available method for routine evaluation of protein quality of VPP and other food products and recommended its acceptance. However, because the methodology used to measure protein quality had broad implications beyond the purview of the CCVP, the Committee recognized the need for the wider scientific community to address issues such as amino acid methodology, protein digestibility, amino acid bioavailability, and correlations in

humans. The Committee accordingly recommended that a Joint FAO/WHO expert consultation should be held in order to review the method. Such a consultation should be requested to review the results of the studies conducted by the Working Group on Protein Quality Measurement and evaluate the protein digestibility-corrected amino acid score method for its usefulness in evaluating protein quality in human nutrition.

21. The Committee agreed to bring the attention of CCNFSDU to the conclusions of the Working group. It also agreed that the deliberations of the consultation as above would have a wide impact on the activities of not only CCVP, but other Codex Committees as well. The Committee thanked the Working Party for its excellent work.

TECHNOLOGICAL JUSTIFICATION FOR THE USE OF PROCESSING AIDS IN THE PRODUCTION OF PRIMARY PROTEIN PRODUCTS AND DISCUSSION OF THE USE OF CERTAIN ADDITIVES IN SECONDARY VEGETABLE PROTEIN PRODUCTS (Agenda item 6)

22. The Committee recalled its discussion on the subject both at its third and fourth sessions. At the third session, it was agreed by the Committee that no food additives should be permitted for use in the preparation of wheat gluten. At the fourth session, the Committee agreed that the U.S.A. in collaboration with the Netherlands and

EUVEPRO, should gather information on the use of food additives and processing aids in primary and secondary vegetable protein products (VPP) and prepare a paper for consideration of the committee at its fifth session.

23. The Committee had before it document CX/VP 89/5 which had been prepared by the delegation of the U.S.A. and also the government comments as contained in CX/VP 89/6.

24. Introducing the document CX/VP 89/5, the delegation of the U.S.A. informed the Committee that the document listed by way of example processing aids and food additives that were used in the primary and secondary forms of VPP and that the presentation was consistent with the decisions taken by the Committee at the 4th Session.

25. The Committee noted that comments received from governments as contained in CX/VP 89/6 were in agreement that food additives were not required either in the production of primary vegetable protein products or primary soy protein products.

26. Several delegations expressed concern on the list of processing aids proposed for use in primary forms of VPP. In some countries, some of the processing aids listed were considered as food additives. Also the philosophy behind listing certain chemicals, which were intentionally used for achieving a technological purpose and which remained behind in the food as processing aids was questioned; the firming agents, calcium chloride and magnesium chloride were cited as examples. Countries trading in VPP would have to face situations of their commodities being rejected as a result of national government classification of certain food processing aids as food additives.

27. The Committee noted that certain chemicals could be considered both as processing aids and as food additives. The delegation of the U.K. and the observer from EUVEPRO proposed that the chemicals listed as processing aids should be reviewed case-by-case and such chemicals which were food additives should be taken out and listed under the Food Additive provisions. EUVEPRO provided such a listing to the Committee in Conference Room Document 1. The delegation of the U.S.A., however, informed the Committee that the processing aids listed, reflected the true situation in the

industry and proposed that the recommendation as contained in page 2 of CX/VP 89/5 be agreed to by the Committee.

28. The Committee agreed to set up a Working Group to consider the recommendation as contained in CX/VP 89/5 and to provide advice to the Committee. The delegations of the U.S.A., the U.K., Switzerland, the Netherlands, Italy, Finland, the Federal Republic of Germany, Canada and the Observer from EUVEPRO participated in the Working Group.

29. The Working Group, after extensive deliberations, proposed the following text that could be included in both the standards for Vegetable Protein Products and Soy Protein Products under the provision for Food Additives.

> "During the course of manufacturing Vegetable Protein Products and Soy Protein Products, the following classes of processing aids, as compiled in the advisory inventory of the Codex Alimentarius Commission may be used.
>
> Acidity Regulators
> Antifoam Agents
> Firming Agents
> Enzyme Preparations
> Extraction Solvents
> Antidusting Agents
> Flour Treatment Agents
> Viscosity Control Agents"

30. The Committee agreed to the above text proposed by the Working Group. The delegations of the U.K., Switzerland, the Netherlands and Finland expressed their reservation to the acceptance of the whole list of processing aids while the delegation of Italy expressed reservation for inclusion of Flour Treatment Agents only.

31. The Committee also agreed to refer the list of processing aids contained in the document CX/VP 89/5 to the Codex Committee for Food Additives and Contaminants for information. The processing aids listed could be considered for inclusion in the inventory on processing aids that the CCFAC was preparing.

32. The Committee expressed its appreciation to the Working Group for its excellent work.

REPORT OF THE WORKING GROUP ON QUANTITATIVE METHODS FOR DIFFERENTIATION OF VEGETABLE AND ANIMAL PROTEINS (Agenda Item 7)

33. The Committee recalled the discussions at its last (4th) session during which it was agreed that it would be very useful to continue work on the collection of data on the methodology for differentiation of vegetable and animal proteins. The delegations of the U.K. and U.S.A. agreed to collaborate with the Netherlands in carrying out this task.

34. The Committee had before it document CX/VP 89/7, which had been prepared by the delegation of the Netherlands.

35. Introducing the document CX/VP 89/7, the delegation of the Netherlands informed the Committee that the document contained a review of literature on the subject up to November 1988 and drew the Committee's attention to the conclusions set out in the document and in particular to the conclusion that it was becoming very evident

that enzyme-immunoassays would be the best approach for effective differentiation of vegetable and animal proteins.

36. The Committee was informed of more recent work on development of a methodology for determination of muscle protein from its content of N-methylhistidine and 5-hydroxylysine. The methodology could be effectively used for determination of non-muscle protein in composite meat products (Agriculture and Food Chemistry, vol. 36, p. 1109-1121, 1988).

37. The Committee expressed its appreciation for the excellent document prepared by the delegation of the Netherlands. It however noted that not one of the available methods was generally applicable for quantitative differentiation of vegetable and animal proteins.

CONSIDERATION AT STEP 7 OF THE PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION OF VEGETABLE PROTEIN PRODUCTS (VPP) IN FOODS (Agenda Item 8)

38. The Committee had before it the above-noted document (Alinorm 87/30, Appendix IV) and CX/VP 89/8, CX/VP 89/8 (ADD. 1), CX/VP 89/8 (ADD. 2), CX/VP 89/8 (ADD. 3) and Conference Room Document 4 containing comments from Canada, Federal Republic of Germany, Ireland, the Codex Committee on Nutrition and Food for Special Dietary Uses, United States of America, Cuba, Denmark, Finland and Mexico.

39. In introducing this agenda item, the Chairman noted that the draft guidelines had been reviewed by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and that Committee had offered a number of comments. Dr. Margaret Cheney (Canada) provided an overview of the recommendation made by CCNFSDU.

Section 3 - Definitions

40. The Committee agreed to delete the existing definition for Vegetable Protein Product (VPP) and replace it by the definition found in Section 2.1 of the Draft Recommended International General Standard for Vegetable Protein Products (VPP).

41. The Committee then agreed to the following revisions of a number of definitions found in Section 3 of the guidelines:

- Available Amino Acids: Amino acids from food proteins that are absorbed and are available for metabolism.
- Bioavailability: The extent to which an amino acid or other essential nutrient is absorbed and available for metabolism.
- 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.
- 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 x 6.25) x protein quality expressed as a fraction (maximum protein quality = 1.0).

42. The following definitions were not amended: Amino Acid Score, Complementation, Limiting Amino Acid, Net Protein Ratio, Protein Quality and Relative NPR (RNPR).

43. After considerable discussion, the Committee agreed to include the following definition for "nutritional equivalence" which had been recommended by the 16th Session of the CCNFSDU:

> "Nutritional Equivalence means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient (s) are present in the substitute or partially substituted food (extender) in comparable amounts".

44. The delegation of the United Kingdom, supported by the Netherlands and the observer from EUVEPRO expressed the view that the inclusion of the concept of nutritional equivalency in the guidelines would create major difficulties for food manufacturers.

Section 6. Uses of VPP to Increase Content of Utilizable Protein

45. The Committee agreed to the following revision of Section 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".

46. After considerable discussion the Committee agreed with the following revision of Section 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"

47. The Committee then reviewed both versions of section 6.6 and decided to accept the longer version which includes sub-sections 6.6.1 and 6.6.2. This decision was made in the interests of providing more advisory information about fortification of VPP with vitamins and minerals.

48. The delegations of the United Kingdom, Italy, the Netherlands and Switzerland expressed a strong preference for the shorter version of Section 6.6, because the longer version could not be comprehensive and might mislead readers into thinking that it was.

49. The Committee agreed with a suggestion of the Delegation of the Netherlands to amend section 6.8 by insertion of the words "of the food". This section now reads as follows:

> "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".

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

50. The Committee had a full discussion about the text of Section 7.1 and finally agreed to the following revision:

"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 nutritional equivalence for the partially or completely substituted food. Where there is demonstrated evidence of public health need, nutritional equivalence should be required".

51. The Committee then decided to amend section 7.2, 7.3 and 7.4 by substituting "nutritional equivalence" for "nutritional adequacy" as follows:

7.2 The nutritional equivalence of a product can be defined in terms of protein quality and quantity and the content of minerals and vitamins. Such a product should be considered nutritionally equivalent if:**(Remainder of the text remains unchanged)**.

7.3 The nutritional equivalence 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 which is nutritionally equivalent with respect to levels of vitamins and minerals, but placing the requirements for protein quantity and quality on the final product, or **(Remainder of the text remains unchanged).**

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

PROPOSED DRAFT GUIDELINES FOR TESTING SAFETY AND NUTRITIONAL QUALITY OF VEGETABLE PROTEIN PRODUCTS

52. Following a short discussion about a proposal to insert the word "novel" before "vegetable", the Committee decided not to amend either the title or text of the above-noted guidelines.

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

53. The Committee decided to advance the guidelines to Step 8 of the Codex Procedure.

REPORT OF THE WORKING GROUP ON CONTAMINANTS (Agenda Item 9)

54. The Committee recalled the discussion at its fourth session during which the possible need for setting maximum levels for contaminants in VPP and SPP was considered. Opinions expressed at that session varied considerably. Some delegations felt that there was no need for setting maximum levels for contaminants since there was no recognized trade problem. Some delegations expressed the view that placing limits on contaminants in primary products was not a meaningful way of protecting the consumer and that limits, where appropriate should refer to food products as consumed. Other delegations indicated that data on contaminants in VPP and SPP might be available that would assist the establishment of maximum limits if required.

55. The Committee agreed that a circular letter be issued seeking information from governments and that the contaminants on which information would be sought should be confined to cadmium, lead and mercury (Alinorm 87/30, paras. 137, 166 and 193). An Ad Hoc Working group led by the delegation of the Netherlands was established to carry out the work.

56. The Committee had before it documents CX/VP 89/9 and Conference Room Document 7 which summarized the results received in response to CL 1987/41 - VP. The document was presented by the delegation of the Netherlands.

57. Presenting the results contained in the documents referred to above, the delegation of the Netherlands informed the Committee that the responses from governments to the Circular Letter were meager. There were wide variations reported by the governments on the content of lead, mercury and cadmium in VPP and SPP and on the basis of the meager results obtained, it would be difficult to set maximum levels for contaminants based on the information received on VPP in general.

58. The Committee expressed the view that the ideal situation would be to set maximum levels for contaminants in VPP and SPP. It noted that such an exercise would assist in the calculation of contaminant intake. It, however, agreed not to establish maximum levels on the basis of the meager information available to it and agreed to include a general statement in the standards for VPP and SPP that emphasized the desirability of minimizing heavy metal contamination. The Committee had no information available to it that contaminant levels in VPP and SPP posed a problem in trade.

59. The Committee agreed to include the following wording under the provision for contaminants:

> "VPP or SPP should be free from heavy metals in amounts which may represent a hazard to health".

60. The Committee noted that there was interest in the area of contaminants in foods and expressed the need to put in efforts for collection of further data on the subject. The delegation of the Netherlands drew the attention of the Committee to Conference Room Document 2, which contained the methodology used in its country for determination of mercury, lead and cadmium in foods and which gave very consistent results. The delegation of Italy presented a document containing methods used in its country for determination of lead and cadmium in foods.

REPORT OF THE WORKING GROUP ON TRYPSIN INHIBITORS AND OTHER ANTINUTRITIONAL FACTORS (Agenda Item 10)

61. The Committee recalled its discussion on the subject at its fourth Session. In its deliberations on the Proposed Draft General Standard for Vegetable Protein Products (VPP) the Committee decided to address antinutritional factors of VPP in a general

statement (Alinorm 87/30, Appendix V, 3.4). However, for its proposed draft standard on soy protein products (SPP), the Committee wished to consider specific limits and analytical methodology for trypsin inhibitor (TI) in SPP and asked a Working Group, led by the U.S.A. and assisted by the Netherlands and EUVEPRO, to prepare a proposal for consideration at the fifth Session.

62. The Committee had before it document CX/VP 89/10. Presenting the document, the delegation of the U.S.A. informed the Committee that the document contained information on (i) Distribution of Trypsin Inhibitors, (ii) Biological effects of Trypsin Inhibitors in Animals, (iii) Trypsin Inhibitor Content of Diets, (iv) Trypsin Inhibitor Content of Soy Protein Products and (v) Effects of Trypsin Inhibitor Inactivation on Protein Functionality.

63. The Working Group had recommended that limits for trypsin inhibitor activity not be set for primary SPP, but if limits were needed they should be defined in terms of the finished product. This was based on consideration that amounts of trypsin inhibitor activity would differ for SPP in international trade because of the variety of functional requirements, that these levels of trypsin inhibitor activity, would generally be reduced during processing of the final food, and of the wide range of contributions that SPP may make to the overall composition of the finished product.

64. The Committee agreed with the conclusions of the Working Group and endorsed its recommendation that the provision for nutritional factors (section 3.4) of the standard for SPP be retained with the insertion of the following sentence between the present first and second sentences: "Where it is necessary to control trypsin inhibitor activity in food, the maximum level allowed should be defined in terms of the finished product".

9.2.6 Trypsin Inhibitor and other Antinutritional Factors

65. The Committee noted that as a consequence of the recommendations of the working Group (Para. 64), Section 9.2.6 of the Draft Standard for Soy Protein Products should be deleted.

66. The delegation of the Netherlands informed the Committee that in its country, a limit for the trypsin inhibitor activity in the finished product was set at 5 mg/g protein. When VPP and SPP is sold as such it should be clear on the label that the product has to be heat treated. The following methodology for determination of trypsin inhibitor activity is under study in the Netherlands:

1. Analysis of low levels of Trypsin Inhibitor Activity in Food, by Jac. P. Roozen and Jolan de Groot. Lebensm - Wiss U Technol. 20, 305, 1987

2. The Trypsin Inhibitor Assay: Improvement of an Existing Method by M.G. van Oort, R.J. Hamer and E.A. Slager. TNO Institute for Cereals, Flour and Bread, Wageningen, the Netherlands.

CONSIDERATION OF THE WORKING GROUP REPORT ON METHODS OF ANALYSIS (Agenda Item 11)

67. The Committee had before it the report of the Working Group on Methods of Analysis as contained in Alinorm 87/30, Appendix VIII and government comments on the report as contained in CX/VP 89/11 and CX/VP 89/11 - ADD. 1.

68. The Committee noted that all the methods, except that for determination of crude fibre had been endorsed by the Codex Committee on Methods of Analysis (CCMAS). The Committee also noted that Type I defining methods were subject to acceptance together with the parameter which they defined. They were linked to the parameter to be

determined and were inseparable from the particular provision to which they applied. Hence provisions could be made for inclusion of only one Type I method in a standard. This was also the case with Type II methods which were obligatory for use only in disputes involving results of analysis.

69. The Committee expressed the view that further discussion of methods endorsed by CCMAS did not seem to be warranted and left the sections under methods of analysis in VPP and SPP standards unchanged. References, however, were updated. There was some discussion whether parameters should be provided for dietary fibre in place of crude fibre. The Committee retained the existing provisions, noting that crude fibre was a quality factor commonly used in the VPP industry, as opposed to dietary fibre, which had nutritional implications. The Committee learned that the subject of providing parameters for dietary fibre under nutrition labelling was under consideration by the CCFL.

70. The delegation of France informed the Committee that it would prefer inclusion of ISO methods when and where available whenever there are differences between AOAC and ISO methods.

CONSIDERATION AT STEP 7 OF THE PROPOSED DRAFT STANDARD FOR VEGETABLE PROTEIN PRODUCTS (Agenda Item 12)

71. The Committee had before it the Proposed Draft General Standard for Vegetable Protein Products as contained in Alinorm 87/30, Appendix V and government comments on the standard as contained in CX/VP 89/12, CX/VP 89/12 - ADD 1, CX/VP 89/12 - ADD 2 and Conference Room Document 3.

3.2.2 Crude Protein

72. The delegation of the Netherlands expressed the view that a value of 40% on dry weight basis for crude protein content of VPP was too low and proposed a value of 50% for consideration by the Committee.

73. The Committee recalled its discussions on the subject at its earlier sessions. The Committee was satisfied that the value of 40% for the crude protein content for VPP was adequately discussed and was a compromise figure and took no action on the proposal of the Netherlands.

74. The delegations of the Federal Republic of Germany, the U.K., France and the Netherlands expressed reservation to the decision of the Committee.

3.2.3 Ash

75. The delegation of France supported by the observer of EUVEPRO informed the Committee that the ash content of sunflower seed meal exceeded 8% and proposed a value of 10% for the maximum ash content of VPP. This proposal was agreed to by the Committee.

3.2.5 Crude Fibre

76. The delegation of France drew attention of the Committee to the fact that the crude fibre content of certain vegetable protein products exceeded 8% and proposed a value of 10% for the maximum crude fibre content for consideration of the Committee. This proposal was agreed to by the Committee,

3.4.1 Minimum Protein Nutritive Value

77. The Committee noted that the methodology for determination of minimum protein nutritive value had yet to be finalized and agreed to delete the provision.

4. Food Additives

78. The Committee agreed to include the text proposed by the Working Group set up to discuss the recommendations contained in CX/VP 89/5, Technological Justification for the Use of Processing Aids in the Production of Primary Vegetable Proteins (See Para. 29).

5. Contaminants

79. The Committee agreed to include the text contained in Para. 59.

80. 8.1.1

The Committee deleted spy from the examples given in the text since based on deliberation at previous Sessions, soy protein products were not covered by the general standard for VPP and were included only in error,

8.9 Non-Retail Containers

81. The present text was deleted and replaced by the text as contained in the Procedureal Manual, 6th Edition. The text would read as follow:

"Labelling of Non-Retail Containers

In addition to Sections 2 and 3 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the following specific provision applies to the labelling of non-retail containers as defined by the Codex Alimentarius Commission (see page 123 of the Procedural Manual, 6th Edition):

Information on 8.1.1 to 8.8 shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents."

9.1 Sampling

82. The Committee noted that the text under this section was not complete and revised it to read the same as in the SPP standard (Alinorm 87/30, Appendix VI, Section 9.1)

The revised text would read as follows:

"(For analytical purposes excluding sampling for net content) According to ISO Method 2170 - 1980 Cereals and Pulses - Sampling of Milled Products".

9.2.6 Heavy Metal Contaminants

83. The Committee deleted this provision since it agreed not to set up maximum limits for heavy metal contaminants (See Para. 58).

84. To a question raised by the delegation of the Netherlands regarding instructions from CCFL, the Committee expressed the view that since there was no evidence that

Vegetable Protein Products were subject to the irradiation process, there was no need to make a reference to irradiation in the VPP standard.

STATUS OF THE DRAFT STANDARD FOR VEGETABLE PROTEIN PRODUCTS

85. The Committee decided to advance the Draft Standard for Vegetable Protein Products, as contained in Appendix III to Step 8 of the Codex procedure.

CONSIDERATION AT STEP 7 OF THE PROPOSED DRAFT STANDARD FOR SOY PROTEIN PRODUCTS (SPP) (Agenda Item 13)

86. The Committee had before it the Proposed Draft Standard for Soy Protein Products as contained in Alinorm 87/30, Appendix VI and government comments on the standards as contained in CX/VP 89/13, CX/VP 89/13 - ADD. 1 and Conference Room Document 5.

3.2.5 Crude Fibre

87. The delegation of France informed the Committee that new Soy Protein Products which contained amounts of crude fibre more than that proposed in the standard were moving in trade and proposed that the Committee should consider increasing the crude fibre levels.

88. The Committee noted that the new soy protein products moving in trade, to which the delegation of France referred to were secondary soy protein products. The Committee agreed not to change the existing figures.

3.4 Nutritional Factors

89. The Committee made the changes in the text agreed to earlier while considering the agenda item on trypsin inhibitors (See Para. 64). The following sentence was inserted between the first and second sentence:

> "Where it is necessary to control trypsin inhibitor activity in food, the maximum level allowed should be defined in terms of finished product".

3.4.1 Protein Nutritive Value

90. The Committee deleted this provision (See Para, 77).

4. Food Additives

91. The Committee inserted the same text as for the food additive provision in the VPP standard (See Paras. 29 and 78)

5. Contaminants

92. The Committee agreed to include the text contained in para 59.

8.9 Non-Retail Containers

93 The present text was deleted and replaced by the text as contained in the Procedural Manual, 6th Edition. The text would read as follows:

> "Labelling of Non-retail Containers
>
> In addition to Sections 2 and 3 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the following specific provision applies to the labelling of non-retail containers as defined by the Codex Alimentarius Commission (see page 123 of the Procedural Manual, 6th Edition):

Information on 8.1.1 to 8.8 shall be given either on the container or in accompanying documents, except that the name of the products, lot identification, and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents."

9.2.6 Trypsin Inhibitor and Other Antinutritional Factors

94. The Committee deleted this provision since it agreed not to set limits for trypsin inhibitor in primary soy protein products. (See para. 64)

9.2.7 Heavy Metal Contaminants

95. The Committee deleted the provision since it agreed not to set maximum limits for heavy metal contaminants in SPP (See Para. 59).

96. The delegation of France, supported by Spain, referred to discussions at the third Session of the Committee and informed the Committee that in their view maximum levels for aflatoxins should be set for Soy Protein Products. The delegation of the Netherlands pointed out that in its country a maximum level of 5 ppb aflatoxin B1 both for food and raw materials has been set.

97. The delegation of the U.S.A. informed the Committee that in its experience aflatoxins were not a problem in soy protein products and hence there was no need to set maximum limits. The Committee recalled that work was in progress in the Codex Committee on Food Additives and Contaminants and the Codex Committee on Cereals, Pulses and Legumes on setting guideline levels for aflatoxins in different commodities and agreed to await the recommendations of those committees before taking any action.

Status of the Draft Standard for Soy Protein Products

98. The Committee decided to advance the Draft Standard for Soy Protein Products as contained in Appendix IV to Step 8 of the Codex Procedure.

REVIEW OF DRAFT GUIDELINES FOR USE OF STANDARDIZED NON-MEAT PROTEIN PRODUCTS IN PROCESSED MEAT AND POULTRY PRODUCTS (At Step 8 of the Procedure) (Agenda Item 14)

99. The Committee agreed that a new Section 5.2 should be added to the above-noted guidelines to provide a clear linkage between the General Utilization Guidelines and the related guidelines developed by the CCPMPP. In particular this reference to the General Utilization Guidelines would introduce the need to consider nutritional equivalence in products where a standardized non-meat protein partially substitutes for meat or poultry protein. The new Section 5.2 would read as follows:

"When a standardized Vegetable Protein Product partially substitutes for the meat protein of a processed meat or poultry product, consideration should be given to the need for nutritional equivalency of the final product as described in Sections 7.1 to 7.3 of the General Guidelines for the Utilization of Vegetable Protein Products in Foods.

100. The Committee agreed with a suggestion from the Chairman that the proposed new Section 5.2 be added to the guidelines and that this be recommended to the Commission.

101. Several delegations expressed the view that the draft CCPMPP utilization guidelines suffered from the lack of a definition for "non-meat protein". The Committee concluded that it would be desirable to include a definition for "non-meat protein" in these guidelines and that this should be brought to the attention of the Commission.

102. Discussion then focussed upon the deletion by the CCPMPP from its guidelines of sub-section (iv) from Section 7.5, which resulted in an inconsistency between the two sets of related utilization guidelines.

103 Several delegations expressed the view that deletion of this sub-section could ultimately result in certain Codex standards becoming meaningless as there would be no guarantee that the meat portion of a product would comply with the applicable Codex standard.

104. The Committee agreed with the proposal of the Chairman that the CCPMPP utilization guidelines be amended by re-introducing sub-section (iv) of section 5 of VPP guidelines and that this recommendation be brought to the attention of the 18th Session of the Commission.

FUTURE PROGRAMME OF WORK (Agenda Item 15)

105. The Chairman noted that the program assigned by the Commission had been completed. However, he suggested that the Committee should continue to serve as a contact point for those seeking information on vegetable proteins. This service could be of particular benefit to developing countries who may wish to obtain this type of information.

The delegation of the U.K. pointed out that, in addition to updating the "Kapsiotis/Wolf" paper (Agenda Item 4), there was also a need to consider future developments respecting the Quantitative Method for Differentiation of Vegetable and Animal Proteins because of rapidly emerging technology. The delegation of the Netherlands was asked by the Committee to serve as a coordinator for this issue and to provide a report to the Canadian Secretariat no later than January 1991, in time for the 19th Session of the CAC. The delegations of the U.S.A. and Canada and the Observer from EUVEPRO agreed to assist the Netherlands with this assignment.

107. In the area of contaminants, the Committee agreed with a suggestion of the Chairman that the CCFAC be asked to consider the question of heavy metal contaminants in vegetable protein products during the course of their deliberations. He also noted that the matter would be brought to the attention of the Commission at its 18th Session. In concluding this agenda item, the Committee concluded that its current business was completed and recommended that it be adjourned sine die and that this recommendation be made to the Commission.

OTHER BUSINESS (Agenda Item 17)

108. The delegation of the Netherlands drew the attention of the Committee to a "Nomenclature of Milk Protein Products" presently under elaboration by the International Dairy Federation and suggested that the development of analogous terminology for all protein products should be considered.

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by:	Document Reference
Codex Standard for Wheat Gluten	8	Governments	CAC/Vol. XIX
Draft Standard for Vegetable Protein Products	8	18th CAC	ALINORM 89/30, Appendix III
Draft Standard for Soy Protein products	8	18th CAC	ALINORM 89/30 Appendix IV
Draft Guidelines for the Utilization of Vegetable Protein Products in Foods	8	18th CAC	ALINORM 89/30 Appendix II

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

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 foods 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 Equivalence: Means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient (s) are present in the substitute or partially substituted food (extender) in comparable amounts.

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 x 6.25) x 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 x 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, 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.

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 connecting 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 equivalence 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 equivalency of the partially or completely substituted food. Where there is demonstrated evidence of public health need, nutritional equivalence should be required,

7.2 The nutritional equivalence 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 equivalence 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 equivalence 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 a 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.

APPENDIX II
ANNEX I

PROPOSED DRAFT GUIDELINES FOR TESTING SAFETY AND NUTRITIONAL QUALITY OF VEGETABLE PROTEIN PRODUCTS [1]

[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).

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 bene 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. 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 animal 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 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.

PROPOSED DRAFT GENERAL STANDARD FOR VEGETABLE PROTEIN PRODUCTS (VPP)

(Advanced to Step 8)

1. SCOPE

This standard applies to vegetable protein products (VPP) intended for use in foods, which are prepared by various separation and extraction processes from proteins from vegetable sources other than single cell protein. The VPP are intended for use in foods requiring further preparation and for use by the food processing industry. This standard does not apply to any vegetable protein product which is the subject of a specific Codex Commodity Standard and is designated by a specific name laid down in such standards.

2. DESCRIPTION

2.1 VPP covered by this standard 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 x 6.25) content of 40% or more. The protein content is calculated on a dry weight basis excluding added vitamins, minerals.

3. ESSENTIAL COMPOSITION AND QUALITY AND NUTRITIONAL FACTORS

3.1 Raw Materials

Clean, sound, plant material essentially free from foreign matter in accordance with good manufacturing practice, or VPP of lower protein content meeting the specifications contained in this standard.

3.2 VPP shall conform to the following compositional requirements except in so far as certain requirements may be modified in specific types of VPP.

3.2.1 Moisture

The moisture content shall be sufficiently low as to ensure microbiological stability under the recommended conditions of storage.

3.2.2 Crude protein

(N x 6.25) shall not be less than 40% on a dry weight basis, excluding vitamins, minerals, amino acids and food additives.

3.2.3 Ash

The yield of ash on incineration shall not exceed 10% on a dry weight basis.

3.2.4 Fat

The residual fat content shall be compatible with good manufacturing practice.

3.2.5 Crude Fibre

For products not covered by a specific product standard, crude fibre shall not exceed 10% on a dry weight basis.

3.3 Optional ingredients

a) carbohydrates, including sugars

b) edible fats and oils
c) other protein products
d) vitamins and minerals
e) salt
f) herbs and spices

3.4 Nutritional Factors

Processing shall be carefully controlled and sufficiently thorough to secure optimum flavour and palatability, as well as to control such anti-nutritional factors as trypsin inhibitor, hemagglutinins, glucosinolates, etc., in accordance with intended use, Where it is necessary to control trypsin inhibitor activity in a food, the maximum level allowed should be defined in terms of the finished product. Certain VPP are produced under low temperature conditions to avoid loss of protein solubility or enzyme activity. These special purpose VPP shall be assayed for protein nutritive value after appropriate heat treatment. Processing must not be so severe as to appreciably impair the nutritive value.

4. FOOD ADDITIVES

During the course of manufacturing VPP the following classes of processing aids, as compiled in the advisory inventory of the Codex Alimentarius Commission, may be used:

Acidity Regulators
Antifoam Agents
Firming Agents
Enzyme Preparations
Extraction Solvents
Antidusting Agents
Flour Treatment Agents
Viscosity Control Agents

5. CONTAMINANTS

VPP shall be free from heavy metals in amounts which may represent a hazard to health.

6. HYGIENE

6.1 It is recommended that the products covered by the provisions of this standard be prepared in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 2, 1985).

6.2 To the extent possible in good manufacturing practice, the products shall be free from objectionable matter.

6.3 When tested by appropriate methods of sampling and examination, the product:

(a) shall be free of microorganisms which may represent a hazard to health;

(b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and

(c) shall not contain any other poisonous substances in amounts which may represent a hazard to health.

7. PACKAGING

VPP shall be packed in suitable hygienic containers which will maintain the product during storage and transport; in a dry and sanitary condition.

LABELLING

In addition to Sections 2, 3, 7 and 8 of the General Standard for the Labelling of Prepackaged Foods (ref. No. CODEX STAN 1-1985) [1] the following specific provisions apply :

[1] Hereafter referred to as the General Standard

1 Name of the Food

8.1.1 The name of the food shall be:

"…….Protein product"

The blank is to be filled with the name of the specific source of the vegetable protein, e.g. groundnut, cottonseed, rapeseed.

8.1.2 The protein content of the VPP shall be declared on a dry weight basis.

8.1.3 The name may include a term which accurately describes the physical form of the product, e.g., "granules" or "bits".

8.1.4 When the VPP is subjected to a texturization process, the name of the product may include an appropriate qualifying term such as "textuted" or "structured".

8.2 Net Contents

The net contents shall be declared by weight in metric units ("Système International") in accordance with Section 4.3 of the General Standard.

8.3 Name and Address

The name and address shall be declared in accordance with Section 4.4 of the General Standard.

8.4 Country of Origin

The country of origin shall be declared in accordance with Section 4.5 of the General Standard.

8.5 Lot Identification

The lot identification shall be declared in accordance with Section 4.6 of the General Standard.

8.6 Instructions for use

Instructions for use shall be given in accordance with Section 4.8 of the General standard.

8.7 Date Marking

The "date of minimum durability" (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and the year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year

only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

of Ingredients

A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

8.9 Non-Retail Containers

In addition to Sections 2 and 3 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the following specific provision applies to the labelling of non-retail containers as defined by the Codex Alimentarius Commission (see page 123 of the Procedural Manual, 6th Edition):

Information on 8.1.1 to 8.8 shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents.

9. METHODS OF SAMPLING AND ANALYSIS

The methods of sampling and analysis referred to hereunder are international methods and apply to the Proposed Standard for VPP.

9.1 Sampling

(For analytical purposes excluding sampling for net content).

According to ISO Method 2170 - 1980 Cereals and Pulses - Sampling of milled products.

9.2 Analysis

9.2.1	Determination of moisture	
	According to the AOAC method 14.002-14.003 (AOAC, 14th Ed., 1984).	TYPE I
9.2.2	Determination of crude protein .	
	According to the AOAC Method 2.057 (14th Ed., 1984)	TYPE I
	Conversion factor 6.25 to comply with definition in Sections 2 and 5.	
9.2.3	Determination of ash	
	According to the ISO 2171-1980 (Method B). Cereals, pulses and derived products - determination of ash.	TYPE I
9.2.4	Determination of fat	
	According to the method No. 1 of CAC/RM 55/1976.	TYPE I
9.2.5	Determination of crude fibre	TYPE I
	According to AACC Method 32-17 (AACC, 1982	TYPE I

PROPOSED DRAFT STANDARD FOR SOY PROTEIN PRODUCTS (Advanced to Step 8)

1. SCOPE

This standard applies to Vegetable Protein Products (VPP) prepared from soybeans (seeds of Glycine Max. L.) by various separation and extraction processes. These products are intended for use in foods requiring further preparation and by the food processing industry.

2. DESCRIPTION

Soy Protein Products (SPP) covered by this standard are food products produced by the reduction or removal from soybeans of certain of the major non-protein constituents (water, oil, carbohydrates) in a manner to achieve a protein (N x 6.25) content of:

- in the case of soy protein flour (SPF) 50% or more and less than 65%;
- In the case of soy protein concentrate (SPC) 65% or more and less than 90%;
- in the case of soy protein isolate (SPI) 90% or more.

The protein content is calculated on a dry weight basis excluding added vitamins, minerals, amino acids and food additives.

3. ESSENTIAL COMPOSITION AND QUALITY AND NUTRITIONAL FACTORS

3.1 Raw materials

Clean, sound, mature, dry seeds essentially free from other seeds and foreign matter in accordance with good manufacturing practice, or SPP of lower protein content meeting the specifications contained in this standard.

3.2 SPP shall conform to the following compositional requirements:

3.2.1 Moisture content shall not exceed 10% (m/m).

3.2.2 Crude Protein (N x 6.25) shall be:

- in the case of SPF, 50% or more and less than 65%;
- in the case of SPC, 65% or more and less than 90%;
- in the case of SPI, 90% or more

on a dry weight basis excluding added vitamins, minerals, amino acids and food additives.

3.2.3 Ash

The yield of ash on incineration shall not exceed 8% on a dry weight basis.

3.2.4 Fat

The residual fat content shall be compatible with food manufacturing practices.

3.2.5 Crude fibre content shall not excèed:

- in the case of SPF, 5%;
- in the case of SPC, 6%;
- in the case of SPI, 0.5%

on a dry weight basis.

3.3 Optional ingredients

a) carbohydrates, including sugars
b) edible fats and oils
c) other protein products
d) vitamins and minerals
e) salt
f) herbs and spices

3.4 Nutritional Factors

Processing should be carefully controlled and sufficiently thorough to secure optimum flavour and palatability, as well as to control such factors as trypsin inhibitor, hemaglutinins, etc., in accordance with intended use. Where it is necessary to control trypsin inhibitor activity in a food, the maximum level allowed should be defined in terms of the finished product. Certain SPP are produced under low temperature conditions to avoid loss of protein solubility or enzyme activity. The special purpose SPP shall be essayed for protein nutritive value after appropriate heat treatment. Processing must both be so severe as to appreciably impair the nutritive value.

4. FOOD ADDITIVES

During the course of manufacturing SPP the following classes of processing aids, as compiled in the advisory inventory of the Codex Alimentarius Commission, may be used:

Acidity Regulators
Antifoam Agents
Firming Agents
Enzyme Preparations
Extraction Solvents
Antidusting Agents
Flour Treatment Agents
Viscosity Control Agents.

5. CONTAMINANTS

SPP shall be free from heavy metals in amounts which may represent a hazard to health.

6. HYGIENE

6.1 It is recommended that the products covered by the provisions of this standard be prepared in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 2, 1985).

6.2 To the extent possible in good manufacturing practice, the products shall be free from objectionable matter.

6.3 When tested by appropriate methods of sampling and examination the product

(a) shall be free from microorganisms in amounts which may represent a hazard to health;

(b) shall not contain substances originating from microorganisms in amounts which may represent a hazard to health; and

(c) shall not contain other poisonous substances in amounts which may represent a hazard to health.

7. PACKAGING

SPP shall be packed in suitable hygienic containers which will maintain the product during storage and transport in a dry and sanitary condition.

8. LABELLING

In addition to Sections 2, 3, 1 and 8 of the General Standard for the Labelling of Prepackaged Foods (Ref. No. CODEX STAN 1-1985) [1] the following specific provisions apply:

[1] Hereafter referred to as the General Standard.

8.1 Name of the food

8.1.1 The name of the food shall be:

"soy protein flour" or "soya protein flour" whn the protein content is 50% or more and less than 65%.

"Soy protein concentrate" or "soya protein concentrate" when the protein content is 65% or more and less than 90%.

"Soy protein isolate" or "isolated soy protein" or "soya protein isolate" or "isolatede soya protein" when the protein content is 90% or more.

8.1.2 The name may include a term which accurately describes the physical form of the product, e.g., "granules" or "bits".

8.1.3 When the SPP is subjected to a texturizastion process, the name of the product may include an appropriate qualifying term such as "textured" or "structured".

8.2 Net Contents

The net contents shall be declared by weight in metric units ("Système International") in accordance with Section 4.3 of the General Standard.

8.3 Name and Address

The name and address shall be declared in accordance with Section 4.4 of the General Standard.

8.4 Country of Origin

The country of origin shall be declared in accordance with Section 4.5 of the General Standard

8.5 Lot Identification

The lot identification shall be declared in accordance with Section 4.6 of the General Standard.

8.6 Instruction for use

The manufacturer of SPP shall provide clear instructions for specific uses claimed on the label.

8.7 Date Marking

The "date of minimum durability" (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and the year will suffice. The month may be indicated by letters in those countries where suchg use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

8.8 List of Ingredients

A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

8.9 Labelling of Non-Retail Containers

In addition to Sections 2 and 3 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the following specific provision applies to the labelling of non-retail containers as defined by the Codex Alimentarius Commission (see page 123 of the Procedural Manual, 6th Edition):

Information on 8.1.1 to 8.8 shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents.

9. METHODS OF SAMPLING AND ANALYSIS

The methods of sampling and analysis referred to hereunder are international methods and apply to the Proposed Standard for SPP.

9.1 Sampling

(For analytical purposes excluding sampling for net content). According to ISO Method 2170-1980 Cereals & Pulses - Sampling of milled products.

9.2 Analysis

9.2.1 Determination of moisture

According to the AOAC method 14.002-14.003 (AOAC, 14th Ed., 1984). TYPE I

9.2.2 Determination of crude protein

According to the AOAC Method 2.057 (14th Ed., 1984). TYPE I

Conversion factor 6.25 to comply with definition in Sections 2 and 3.

9.2.3 Determination of ash

According to the ISO 2171-1980 (Method B). Cereals, pulses and TYPE I

derived products - determination of ash.

9.2.4 Determination of fat

According to the method No. 1 of CAC/RM 55/1976. TYPE I

9.2.5 Determination of crude fibre

According to ISO 5498. Determination of crude fibre content - general method TYPE I