codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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DISCUSSION PAPER ON ISSUES SURROUNDING ELABORATION OF A CODEX GUIDELINE FOR VITAMIN AND MINERAL SUPPLEMENTS

Prepared by representatives of the Delegations of Brazil, Canada, European Commission (EC), Mexico, and the United States of America (USA)

BACKGROUND

The Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) agreed, at its Seventeenth Session, that the development of guidelines for vitamins and minerals would be appropriate. The Delegation of Germany offered to prepare a working paper on Vitamin and Mineral Supplements for consideration by the CCNFSDU. The CCNFSDU discussed the paper at several Sessions and at its Twentieth Session forwarded Proposed Draft Guidelines for Vitamin and Mineral Supplements to the Commission for adoption at Step 5.

After considerable discussion at its Twenty-second Session, the Commission agreed to return the guidelines to Step 3 for further comments and consideration by the CCNFSDU, including reconsideration of the need for the guidelines.

At its Twenty-first Session, the CCNFSDU decided that a second paper presenting the issues that arise regarding regulation of vitamin and mineral supplements would be useful in furthering the discussion. The CCNFSDU requested that a discussion paper be prepared jointly by the delegations of Canada, the EC, and the USA. The delegations of Brazil and Mexico also became drafting partners in the preparation of the discussion paper.

ANNEX

The attached annex represents the joint effort of the five delegations that prepared this discussion paper. It does not represent the opinion of any one delegation. Rather, it attempts to present a summary of issues that have arisen in discussions relating to the regulation of vitamin and mineral supplements and to present those issues in a neutral and objective manner that will further understanding of the rationale behind the various approaches to these issues.

ANNEX

DISCUSSION PAPER

on

ISSUES SURROUNDING ELABORATION OF A CODEX GUIDELINE FOR VITAMIN AND MINERAL SUPPLEMENTS

Prepared for the Codex Committee on Nutrition and Foods for Special Dietary Uses

By a working group consisting of representatives of the Delegations of Brazil, Canada, EC, Mexico, and USA

CONTENTS

INTRODUCTION

1.The Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) has devoted considerable time to developing proposed draft guidelines for vitamin and mineral supplements. The 16th session of the CCNFSDU (1988) agreed to seek the approval of the Commission to undertake work on food supplements. The Commission at its 18th session in 1989 agreed to send out a Circular Letter seeking government views on whether work on vitamin and mineral supplements should be undertaken within the Codex system. At that time there was general support for the development of guidelines. The 17th session of the CCFNSDU (1991) agreed that the development of guidelines for vitamin and mineral supplements identified as foods would be appropriate. The Delegation of Germany offered to prepare a working paper on Vitamin and Mineral Supplements for consideration by the CCNFSDU. As a result of issues arising in discussion of this working paper, at its 21st Session the Committee decided that a second paper would be useful in furthering the discussion. The Committee asked that a discussion paper be prepared jointly by the delegations of Canada, the USA and the EC. These delegations were assisted in preparing this document by the delegations of Brazil and Mexico. For use as a basis for the new document, the Committee was provided with a discussion paper prepared by the responsible services of the EC, which

contained discussions of some of the issues relevant to regulation of vitamin and mineral supplements.

2.The CCNFSDU decided that at this stage the guidelines at issue should cover only vitamin and mineral supplements (19th Session, 27-31 March 1995, para. 46). Vitamin and mineral supplements are generally products marketed as concentrated sources of these nutrients, alone or in combination, whose purpose is to supplement the intake of these nutrients from the normal diet. They are usually marketed in capsules, tablets, powders, liquids, etc. Consistent with the decision of the 19th Session of the Committee, this paper addresses products intended to provide supplementation only with vitamins and/or minerals. It does not address products intended to provide supplementation with other nutrients (e.g., amino acids and essential fatty acids) and other food components (e.g., some plant extracts and botanicals). In addition, taking into account that some countries regulate these products as foods and others as drugs, the Committee agreed(19th Session, para. 46) that a Codex guideline would apply to vitamin and mineral supplements which are considered in national legislation to be foods. This position is consistent with the limits of the mandate of the Codex Alimentarius Commission, which does not cover drugs.

3. This paper attempts to provide a neutral and objective presentation of the issues that arise regarding regulation of vitamin and mineral supplements. It is aimed at furthering the understanding of the rationale behind the various

approaches to these issues. The paper is structured around a series of ten topics or issues related to regulating vitamin and mineral supplements and highlights the various approaches to each topic. The topics are: the purpose and role of vitamin and mineral supplements, products to be covered by a guideline and terminology to describe the covered products, positive and/or negative lists of nutrients, maximum levels, minimum levels, purity criteria, good manufacturing practices, labelling, packaging, and marketing.

PURPOSE AND USES OF VITAMIN AND MINERAL SUPPLEMENTS

4. A variety of the issues surrounding the development of a guideline for vitamin and mineral supplements are rooted in the fact that the purpose and role of vitamin and mineral supplements vary among countries and among interested groups (e.g., consumers, manufacturers, health professionals). Some indicate that studies show that in many countries changing lifestyles, at the individual and family level, have greatly influenced eating habits. There is less time or desire for having full meals and a consequent increase of consumption of snacks and “fast food” products. Others point to studies that reveal that aging or a more sedentary life may result in a reduction of food intake because of reduced energy requirements. Reduction in food intake can also be the result of, justified or not, weight reduction diets, over short or prolonged periods. Because of these and other changes in dietary habits, concern is often voiced about the adequacy of intakes of vitamins and minerals from food. In addition, current science has identified nutritional

needs in certain subpopulations that may be difficult to meet with the normal diet alone, for example, the need of postmenopausal women for calcium.

5. Despite the changing lifestyles and food consumption patterns in many countries, many others believe that education and proper motivation will ensure an adequate diet. They are convinced that a varied diet can, under normal circumstances, provide all the necessary nutrients for growth, development, and maintenance of health. However, questions arise as to whether, for certain groups of the population, “normal circumstances” are always applicable. It is generally recognized that the nutrient content of national food supplies varies for a number of reasons, including geographical and climate differences and different nutrients in the soil. In addition, national nutritional goals and public health policies vary.

6. Vitamin and mineral supplements are identified by various groups as having a variety of uses, including:

- to correct a frank nutrient deficiency;
- to ensure that recommended intakes of vitamins and minerals are achieved, whether or not the diet is truly deficient;
- to supplement a less than optimal diet, and particularly to satisfy those needs identified by recently established science that supports intakes higher than those that have been traditionally recommended to avoid deficiency ;

- to provide high levels of those nutrients that have been associated with possible reduction in risk of chronic disease;
- to meet consumer demands that go beyond the benefits documented by science.

7. Each of these intended uses, coupled with the presentation of the product, can trigger different regulatory approaches by making a product a drug in some countries or a “quasi-drug” in others, as opposed to a food. In places where they are regulated as foods, vitamin and mineral supplements may or may not be considered as different from ordinary foods and therefore may or may not require separate regulatory policies.

8. It is widely believed that consumers buy vitamin and mineral supplements having made a conscious choice. In some countries it is believed that this choice should not be denied to the consumer, provided the necessary rules (which differ from country to country) guaranteeing the safety of the product are met and proper information for the consumer is available. However, in other countries there is concern that good dietary habits may be adversely affected by the increased availability and promotion of vitamin and mineral supplements. It is feared that good nutritional behavior by the population may be upset. This is of particular concern in countries where considerable resources have been devoted to developing good habits. Some may consider that choosing supplements as a significant source of vitamins and minerals might affect nutrient balance as well as the intake of food and

therefore of other nutrients, including fiber, macronutrients, and other unidentified components in food products.

PRODUCTS TO BE COVERED BY A GUIDELINE AND TERMINOLOGY TO DESCRIBE THE COVERED PRODUCTS

9. CCNFSDU has already devoted a significant amount of discussion to the issues associated with the development of guidelines and the identification of appropriate terminology to describe the products. The Twenty-first Session of the Committee had before it a document entitled “Proposed Draft Guidelines for Vitamin and Mineral Supplements.” This term, “vitamin and mineral supplements,” was decided upon after discussions at the two previous sessions. The Committee decided at the Twentieth Session that it would consider addressing vitamins and minerals and not other nutrients or food components. For consistency, this paper uses the Committee’s terminology to refer to the subject products and the contemplated guideline, but it does not recommend any particular terms over others.

A. Products to be covered by a guideline

10. It has been noted that laws in different countries apply different legal status to products referred to in Codex as "vitamin and mineral supplements." In some countries all "supplements" are regulated as drugs. In others, some "supplements" are regulated as drugs or "quasi drugs" depending on the intended use or the level of the vitamins and/or minerals in the product, while other "supplements" are controlled under food legislation. Because the mandate of Codex covers only foods, any Codex guideline and the harmonization to be achieved by it would concern only products considered to be foods and would not be applicable to products regulated as drugs.

11. Questions arise as to the overall scope and applications of a guideline. The Committee has determined that, if developed, the scope should focus on those supplement products containing only vitamins or minerals singly or in combination. However, when the suggestion is made to use "vitamins and minerals" in the name of a Codex guideline, different concerns are expressed:

- There is concern that a guideline addressing only vitamins and minerals as the food components of products covered by the term "supplements" would prohibit all other components that could be included in such products because they would not be included in the guideline.
- Others question whether the provisions in a guideline developed for products with only vitamins and minerals would also be applicable to the

vitamin/mineral products mixed with other food components, like herbs and other botanicals also intended to provide supplementation to the diet.

- Some are concerned that if CCNFSDU were to develop a guideline for vitamins and minerals, the principles and/or provisions of such a guideline would by practice be extended to the other components used to provide supplementation. They believe that provisions developed solely for vitamins and minerals might not be suitable for guidelines for other components intended to supplement food intake.

Some who agree that the contemplated guideline should be limited to vitamins and minerals suggest that the committee should clarify that excluding other components from the guideline does not address the acceptability of those components in the supplement products. Another position is that if a guideline is developed by the CCNFSDU, it should be developed to cover all components intended to supplement food intake, not just vitamins and minerals.

12. Most consider that vitamin and mineral supplements are intended to be additions to the normal diet and are intended for the population at large or a very wide spectrum of consumers. However, a number of such products are intended for specific groups of persons to satisfy particular nutritional requirements of these persons, such as pregnant women, infants or persons with special medical needs. These products would therefore be foods for special dietary uses as defined in the relevant Codex General Standard (Codex Standard 146-1985).

13. It is argued that these targeted products should, because of their nature, be subject to the specific rules applicable to foods for special dietary uses, as the case may be, and consequently not be in the scope of a guideline on vitamin and mineral supplements. Others would disagree with this view and believe that vitamin and mineral supplements that serve a special dietary purpose should be considered to be a subgroup of the whole body of vitamin and mineral supplements. From this perspective, most provisions of a guideline should be applicable to vitamin and mineral formulations intended for special dietary use and that the relevant standard for the special dietary use would impose additional appropriate requirements.

B. Terminology to describe covered products

14. The Committee originally used the term “dietary supplements” in its draft guideline. The terminology was changed to “vitamin and mineral supplements” by the 20th session of the CCNFSDU, when the decision was made to limit the guideline to vitamins and minerals. As evidenced by the discussions, the term “dietary” has a broad meaning to some, in one sense applying to the diet in general, and in an even broader sense, referring to any dietary substance, even those that are not solely nutritive substances. On the other hand, others have reserved the term “dietary” for articles that serve a particular dietary purpose. Some suggest that supplements should be

described as “food supplements” because these products supplement the normal intake of food.

POSITIVE AND NEGATIVE LISTS

15. There are differing opinions as to which vitamins and minerals should be allowed in supplements. Some think there should be considerable liberty for the manufacturer to decide the composition of the product, while others believe there should be restrictions. The restrictions used in some countries include lists of the vitamins and minerals permitted to be in supplements (positive lists) and lists of substances for which use in supplements is prohibited (negative lists).

A. Lists of nutrients

16. A positive list of nutrients would exclude from supplements any vitamins and minerals not listed. Criteria cited for developing such a list include: (1) limiting the list to vitamins and minerals recognized on the basis of generally accepted scientific data as essential in human nutrition; and (2) limiting the list to those vitamins and minerals not normally found in abundance in the diet. A list of all essential vitamins and minerals would be more comprehensive than a list that excluded those essential nutrients that were abundant in the diet. Only those vitamins and minerals for which there was identifiable risk of deficiency would be on the second list. It is thought that if the vitamin or

mineral were abundant in the diet, consumers would be spending money for products from which they are unlikely to derive measurable benefit. Some believe the positive list could also be used to prohibit use of vitamins or minerals thought to have a very narrow safety range, e.g., arsenic.

17. Some disagree with positive lists because they believe that consumers should be able to choose among the full range of vitamins and minerals and that these supplements should not be prohibited unless there is a danger to health. Some substances that are toxic at certain levels, e.g., vitamin D and selenium, are recognized as essential and safe at lower levels of intake.

18. Regarding prohibiting use in supplements of vitamins and minerals normally abundant in the diet, opponents of positive lists believe that determinations regarding abundance in the diet cannot realistically be made at the international level. Such determinations can only be made at the national level, and then only with difficulty. They believe that even at the national level, it is unlikely that for a particular nutrient every segment of the national population has abundant intake. For example, elderly women may need assistance in obtaining adequate calcium. The consumer should therefore be allowed to decide whether to supplement with vitamins and minerals.

19. There are consumers who believe that they should be able to choose among the full spectrum of vitamin and mineral supplements and that there

should be no limitation on dosage. They believe these products should be available as foods and not restricted as drugs.

20. Negative lists identify substances that should not be permitted in vitamin or mineral supplements. Any substance not on the list could be used, if it is safe and the product is properly labeled. Thus, while the concern that lists would limit choices applies to both positive and negative lists, negative lists would be less limiting than positive lists. Negative lists of vitamins and minerals would provide more flexibility in choosing ingredients for vitamin and mineral supplements.

B. Lists of sources of nutrients

21. Positive and negative lists are also viewed by some as important to control the sources of the nutrients allowed in supplements. There are different chemical forms of a nutrient that can be used in the manufacture of supplements. For example, there are several calcium salts commonly used as sources of calcium and there are several compounds used to provide vitamin A in supplements. Those proponents express concerns that some sources may be toxic. They also cite the need to ensure that the nutrient is bioavailable. The consumer would derive no benefit from a product, which, although it announces the presence of a nutrient, does not make it available to the organism. However, opponents of the lists believe that the bioavailability of a nutrient from different sources does not depend only on the

source and it is a rather complex matter. Opponents also state that a comprehensive listing of acceptable vitamin and mineral sources would be difficult to develop. Further, once a list is established, it would be cumbersome to modify it to substitute an equally bioavailable and useful source not already on the list. This could be detrimental to innovation. Some support the consumer's right to choose from a wide variety of sources of vitamins and minerals. For example, calcium can be obtained from salts like calcium carbonate and calcium citrate, but some consumers prefer calcium from sources like bone meal or oyster shell.

MAXIMUM LEVELS

22. One of the most controversial issues relates to the maximum levels for vitamins and minerals allowed to be present in food supplements. It is beyond doubt that intakes above a certain level of some vitamins and minerals can lead to undesirable or adverse health effects. These can be acute toxic effects following a massive amount of the nutrient concerned (e.g., iron consumed by young children) or can be severe toxicological effects following intakes of high amounts over long periods of time (e.g., preformed vitamin A, selenium). Other milder effects, but still undesirable, have been described following high dose intakes of other vitamins (e.g., vasodilatation (flushing) with niacin, yellowing of subcutaneous fat with carotene, etc). Some cite concerns that intakes above a certain level of some vitamins and minerals for a long period of time can lead to undesirable or adverse

health/physiological effects, such as folic acid's potential to mask vitamin B12 deficiency. And still some others are concerned that excess intakes of minerals and trace elements may lead to interactions among them and with other nutrients, potentially causing an adverse effect on their absorption and metabolism, depending on a number of conditions and other parameters (e.g., timing of intake, composition of meals, etc.).

23. Maximum limits for those nutrients that have well known capacity for causing adverse effects (e.g. vitamin A, vitamin D, niacin, and selenium) would seem to be generally acceptable. Conversely, nutrients such as thiamin, riboflavin, biotin, pantothenic acid, vitamin B-12, vitamin C, and vitamin E, have extremely low toxic potential. Some believe that setting safety limits for them would be an idle gesture. Others, though, believe that maximum levels should be set for all vitamins and minerals in supplements.

24. Different views have been expressed as to the basic principle to be used in establishing maximum limits for vitamins and minerals. One view suggests that limits should be set only on the basis of scientific risk assessment so that consumers can choose from the widest range of safe products. Another view is that maximum limits should be based on nutritional considerations and be set at 100% of the recommended nutrient intake level or low multiples thereof.

A. Limits Based on Nutritional Needs

25. Proponents of nutrition-based limits point out that the nutritional needs of over 90% (ranges from 90% to 97.5%, depending on national policy) of the population would be covered by a daily intake of the nationally recommended level for vitamins and minerals. They would argue that it is therefore appropriate that maximum limits for the products in question, which, they emphasize, are foods, should be based on nutritional needs. Taking into account individual variations and possible health benefits from higher intakes on the one hand and the risks associated with excess intakes of some nutrients and the proliferation of vitamin and mineral supplements from the other, some of them would accept limits which would not exceed one or few multiples of the recommended intake level, depending on the nutrient. From their perspective, this would eliminate any potential hazard from unknown risks. In addition, using a nutritional needs basis for setting maximum levels of vitamins and minerals in supplements would prevent consumers from being misled to purchase products that would give them little or no benefit. It should be noted that in some regulatory approaches nutrition-based limits would not totally prohibit products containing higher levels of a vitamin or mineral from being marketed, but instead would cause the product to be regulated as a drug.

26. Supporters of safety as the basis for maximum levels believe that limits should be based only on genuine safety considerations using accepted risk assessment procedures and not on nutritional policy related to currently

known benefits. They claim that the safety of foods is the primary basic principle of food legislation and that if vitamin and mineral supplements are to be regulated under food law the safety of these products should be the only determinant for setting maximum levels for vitamins and minerals. Some nutrients will be toxic at levels close to their recommended intake level, while others will exhibit no toxicity at levels far above the recommended intake level. The belief is that consumers should be allowed to choose among products containing different levels of vitamins and/or minerals when such levels do not pose a hazard to health. It has been suggested that limits should be set at values that are calculated to be safe and that provide a margin of safety below the amounts that are harmful.

B. Limits Based on Scientific Risk Assessment

27. Supporters of the safety approach state that vitamin and mineral supplements may contain vitamins and minerals up to a level that is considered safe on the basis of risk assessment considerations as determined by appropriate methodology and must take into account exposure to nutrients from all sources including nutrients from foods (naturally occurring, food additives, food fortificants), water and supplements. Some indicate that risk assessment frameworks have traditionally been developed to assess the risks of chemicals such as environmental contaminants and food additives and that risk assessment of nutrients is different because unlike other substances, nutrients are essential for life and benefits of intake as well as risks must be considered.

28. The development of frameworks for risk assessment of essential nutrients is an area of much activity worldwide. Examples of existing risk assessment models for vitamins and minerals include that used by the Food and Nutrition Board, Institute of Medicine, National Academy of Sciences to develop tolerable upper intake levels in the ongoing review of Dietary Reference Intakes ("Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients," Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, Washington, D.C. 1998). The Health Protection Branch (HPB) of Health Canada has developed a four-step Nutrient Risk Assessment model for vitamins and

minerals ("Report on Calcium Risk Assessment, Parts I and II: Hazard Identification and Hazard Characterization," Food Directorate, Health Protection Branch, Health Canada, October 1997). Other frameworks are now under development by the WHO, the EU and the UK. Upper safe limits have been or are being established by a number of authoritative scientific bodies in different parts of the world.

29. If the risk assessment-based approach were to be used, a number of issues concerning the methodology or process for arriving at safe maximum levels present in food supplements need to be discussed. Although current risk assessment models used for nutrients are generally based on the FAO/WHO The Application of Risk Analysis to Food Standard Issues (FAO/WHO, ALINORM 95/0, Appendix 5) and include similar components of risk estimation such as hazard identification and characterization, exposure evaluation and risk characterization, there are a number of differences in the application of these components. Therefore, there are or may be differences in the result arrived at by the different bodies. For example, some models consider the adverse effects as non-threshold while other models use threshold effects and apply a variety of safety factors. The different models also use various methods to handle uncertainties of intakes or population variability. In many cases scientists lack good data, so that even when attempting to apply the same scientific risk assessment procedure, the level of the nutrient determined to be potentially harmful can vary. The data problems include, but are not limited to, changing health end points in studies

and differences in sensitivity among studies. In addition, there are differences in how the data that underlie the determination of a safety level for a nutrient are evaluated. For example, if one study is given a certain weight by one evaluating body and a significantly different weight by another body, the two bodies can reach different conclusions, even using the same safety evaluation procedure. These different conclusions would likely result in different policies for the same nutrient. Care should be taken in the case of nutrients that could be toxic at levels close to their recommended intake level, to avoid situations where maximum permitted levels would be below recommended intakes.

C. Quantity of Product as Basis for Limits

30. There is considerable agreement concerning the amount of the product on which to base limits. As described above, this paper deals with supplements in tablet, capsule, powder and small volume liquid forms. In this context, it is likely that general agreement can be easily obtained to base nutrient calculations on the amount of the supplement in the daily dose recommended on the label by the manufacturer, e. g., 1 tablet per day, 2 capsules per day. The several possible bases for foods, weight, energy, and serving size, are not relevant for supplements as covered in this paper because of the forms in which they are sold. This daily dose basis would also be applicable for minimum limits (discussed below) if they were to be developed.

MINIMUM LEVELS

31. It is generally agreed that the purpose of a vitamin or mineral supplement is to provide products with meaningful levels of the nutrients present. Therefore, it would be misleading to the consumer to make available a supplement that provides an insignificant amount of the vitamin or mineral. The difficulty in setting the limit is in the definition of the word “meaningful.” For most, it typically relates to the recommended intake level. Some would set a single figure, e.g., 15% or 30% of the recommended intake level, as the amount of each vitamin and mineral present necessary to make the contribution meaningful. They believe the minimum should be at such relatively high levels because the products are represented as concentrated sources of the vitamins and minerals. However, others prefer that any minimum be set on a case-by-case basis rather than across all vitamins and minerals. They point out that given the wide variation in nutritional requirements and dietary intakes for different nations (and subpopulations, age and gender groups within those nations) it would be difficult if not impossible for percentages of set recommended daily intakes to be both appropriate and universally valuable as references for limits. In addition, technical difficulties have been cited that likely would result from a uniform minimum for all vitamins and minerals, particularly a limit as high as 15% or greater of the recommended intake level. For example, the amounts of some

nutrients, such as calcium and magnesium, may be technologically limited in multivitamin/mineral products because of their bulk.

PURITY CRITERIA

32. Some believe that where supplements are foods, the purity criteria for a given substance should be the same when it is used in a supplement as in a conventional food. Others like the drug approach and claim that the vitamins and minerals used in supplements are purchased to the standards given in recognized pharmacopoeia. Such references are also given in Codex standards (e.g., on infant formula). However, some of the source compounds for vitamins and minerals are also used as food additives. The purity criteria for substances used in food manufacture are generally even stricter than the ones applicable to substances used in making drugs, which are used in the majority of cases occasionally and for a limited period of time. The complexity in this approach arises where the source compound is not on the Codex list of approved food additives and there is consequently no approved Codex set of purity criteria for the compound. What purity criteria would be appropriate? A mixture of international references including but not limited to those of JECFA, EU Pharmacopoeia, US Pharmacopoeia, EU legislation, FCC (Food Chemicals Codex) may be appropriate. The multiple reference approach would also be favoured by industry who argue that one reference would not cover all substances, not reflect current practice and severely disturb production lines.

33. Still others believe that purity criteria specific to supplements may be more appropriate than either food- or drug-based purity criteria. While there is general agreement that purity criteria are necessary, there are concerns about the appropriateness of the standards. The concerns are that purity criteria based on those for foods or drugs might be stricter than or different from what is feasible for manufacturers to achieve within the limits of source materials and feasibility of manufacture.

GOOD MANUFACTURING PRACTICES (GMPs)

34. There is widespread agreement that vitamin and mineral supplements should be manufactured under appropriate GMPs to ensure wholesome and useful products. It is through good manufacturing practices that a manufacturer of a vitamin/mineral supplement establishes and maintains the identity, purity, potency and hygiene of the product. However, the question arises as to whether elaboration of good manufacturing practices is an appropriate topic for a Codex guideline. If good manufacturing practices is a proper subject for the work of a Codex committee, perhaps a Code of Practice is a more appropriate vehicle.

35. As to the nature of GMPs, some believe that supplement GMPs should be based on GMPs for foods and not drug GMPs, particularly GMPs for prescription drugs. Food GMPs would use strict purity criteria and other

measures, but the control and validation aspects would be less than for drugs. This is because the risks associated with deviations from procedures for supplements are considerably less than those associated with manufacturing deviations for drugs (i.e., less adverse pharmacological impact). Others, who support stricter criteria, indicate there is more need for concern for dietary supplements because the exposure is greater than for drugs. As with purity criteria, there is also the opinion that because the consumption rate for vitamin and mineral supplements is different than those for foods and drugs, supplement GMPs should be specific to the supplements and not based on either food or drug GMPs.

LABELLING

A. General requirements

36. While some aspects of labelling are relatively non-controversial, other aspects of labelling result in considerable debate. Many believe that the supplements should be subject to most of the labelling requirements for other foods (as elaborated in the Codex General Standard for Labelling of Prepackaged Foods). That is, the requirements that foods bear a name, net contents statement, list of ingredients, the name and address of the responsible firm, and expiration date are equally applicable to vitamin and mineral supplements regulated as foods. The General Standard would also require that vitamin and mineral supplements bear directions for use.

37. There have been discussions as to whether the source compounds for vitamins and minerals should be declared on the label. If it were to be agreed that the general requirements for labelling of food should apply to vitamin and mineral supplements, the ingredient declaration requirements in that standard would apply. Under the General Standard for Labelling of Prepackaged Foods each ingredient must be declared by its name on the label. While the product would be promoted as containing the vitamin and /or the mineral form, and any nutrition labelling would use the nutrient terminology, the name of the source compound, i.e., the ingredient actually used in formulating the food, would have to be included in the declaration of ingredients.

B. Nutrition labelling

38. Under the Codex Guidelines on Nutrition Labelling, nutrition labelling is not mandatory for all foods. The guidelines state that nutrient declaration should be mandatory on foods for which nutrition claims are made. However, some parties are of the opinion that vitamin and mineral supplements should be required to bear nutrition labelling because nutrient contribution is their sole value. Some believe that current provisions for nutrition labelling for foods can be interpreted and used directly for vitamin and mineral supplements while others suggest that because vitamins and minerals are different from foods, specific provisions are needed.

39. Those who argue that nutrition labelling for foods as laid out in the Codex Guidelines on Nutrition Labelling is not appropriate for supplements, raise a number of questions as to what should be included in the nutrition label of a vitamin/mineral supplement. The food nutrition label includes declaration of the amount of protein, fat, carbohydrates and energy. The question arises as to whether the supplements should also declare these components. Some say that these components are not relevant to the forms in which vitamin and mineral supplements are sold because the supplements do not provide significant amounts of protein, fat, carbohydrate or energy. Thus these components need not be declared. They contend that the vitamins and minerals present in the supplement are the only nutrients appropriate for the nutrition label. They further recommend that the amount as well as the percentage of the nutrient reference value of each vitamin and mineral be stated in the nutrition label of a supplement. (Note: The nutrient reference value was established by Codex as a label reference value to be used by manufacturers to declare and by consumers to evaluate nutrient content of foods. It does not serve the same purpose and is not necessarily the same level as the recommended intake level for a nutrient.)

40. Those who favor applying existing guidelines to vitamin and mineral supplements suggest that the name of the supplement as required by the General Standard for labelling would constitute a nutrition claim. They state that nutrition labelling would therefore be required for the product under existing guidelines. Additionally, under the current guidelines, where the

product does not contain a declarable amount of the four mandatory nutrients (i.e., energy, protein, fat, and carbohydrates), no declaration would be required for the four. Proponents for this approach indicate that the guidelines specify that the amount of "any other nutrient" for which there is a nutrition claim should be declared, and therefore, all vitamins and minerals in the supplement would fall under this provision and would be declared.

C. Claims

41. Though some do not consider claims to be appropriate for vitamin and mineral supplements, for those that support claims, there are differences of opinion as to whether these products should be subject to the same guidelines addressing claims as foods. Some believe that a vitamin/mineral supplement should be allowed to bear all claims permitted for foods for which the supplement qualifies. Others consider that there may be a need for special provisions or limitations for claims on vitamin and mineral supplements. They question, for example, whether supplements should be allowed to bear nutrition claims or function claims and, if so, whether there should be provisions for supplements different from those for conventional foods. Some believe that claims for vitamin/mineral supplements should be subject to different definitions than foods, for example, because they are concentrated sources of the nutrient, claims should not be allowed unless the supplement provides at least 30% per day of the recommended intake level for the nutrient. In addition, there is considerable discussion ongoing in

Codex about claims regarding reduction of risk of chronic disease (sometimes called “health claims”). If Codex were to develop principles and provisions for use of this kind of claim on foods, it would be necessary to also decide whether and how these claims should be used on vitamin and mineral supplements.

D. Special statements and warnings

42. Questions arise regarding special statements and warnings on vitamin and mineral supplements. Some parties suggest that requirements for specific statements should be considered (e.g., “a varied diet will provide all the vitamins and minerals you require,” and “you should not consume more than the recommended intake level”). This is because such statements help the consumer place these products within the context of the total diet and help consumers recognize potential adverse effects. Others disagree with use of such special statements for vitamin/mineral supplements on the basis that they could mislead consumers or are otherwise inappropriate. They suggest that emerging science indicates that there may be benefit from some vitamins and minerals at intake levels above those currently recommended and achievable from the diet.

43. Some suggest that there should be warnings on products for which the potentially hazardous level is near the recommended intake. Others object to wide use of warning statements on vitamin and mineral supplements. They

believe that if a product presents a hazard under normal conditions of use it should be prohibited. They believe that warning statements are appropriate only for products that may be unsafe for some but not all consumers or under unusual use patterns. This position is also based on the concern that warnings, under these circumstances, cannot be properly interpreted by consumers and that, as well, too many warnings could result in consumers not paying attention to them.

PACKAGING

44. Many generally agree that vitamin and mineral supplements should be in packages that will:

- Retain the product potency/activity through the expiration/best before date
- Protect children from those products that may pose a health risk to children
- Safeguard the product from environmental contamination
- Provide evidence of tampering with the integrity of the product or the package.

However, they believe that the needs of different peoples in different regions vary so greatly that uniformity in criteria for these package functions would be difficult to achieve. For example, there are a number of cases each year of children suffering adverse effects from overdose of food supplements. The vast majority of such cases relate to the consumption by infants and young children of iron supplements prescribed to mothers during pregnancy. The

approach to the problem could be either to require child resistant closures (CRCs) to be fitted to containers of iron supplements with high iron contents, or to limit the total amount of elemental iron per container. Most manufacturers of children's supplements already use CRCs with the majority of these products on a voluntary basis. The labels on many of these products already contain a statement that the container should be kept out of sight and reach of children. There may be a case for the mandatory use of CRCs for those products containing high levels of nutrients. There are however high costs in producing CRCs and research has shown that CRCs have proven more difficult for the elderly to open than for children. If there is a case to require the use of CRCs, it may therefore be more practicable to limit this requirement to products containing specific nutrients.

MARKETING

45. In addition to the issues discussed above, the structure and functioning of the food control authorities is another factor that influences access of vitamin and mineral supplements to the market. Some authorities claim that there are so many supplements that it is very difficult to control them for safety, labelling requirements, claims, etc. Others are greatly concerned that it would be very difficult to monitor the impact of vitamin and mineral supplements on the intake of these nutrients on the population and act swiftly, where necessary, to prevent undesirable situations from developing. In fact, structures and methodology for food and nutrition surveillance vary greatly.

This is why many authorities require either prior authorization of each product or notification at the time of placing the product into the market in order to enable the creation of a register of vitamin and mineral supplements.

46. On the other hand, parties who believe consumers should be allowed to make informed choices from a wide range of vitamin and mineral products also tend to believe that market forces should be allowed to determine the marketing methods that are most appropriate.

47. Should provisions for vitamin and mineral supplements be agreed upon and placed in a Codex guideline, products conforming to the guideline would be marketable in those countries adopting the guideline. Consistent with established principles, practices of prior authorization would no longer be necessary, and it is argued that any such practices remaining after adoption of a guideline would reduce the effectiveness of the harmonization efforts in the guideline. However, some would consider it desirable to maintain, if not prior authorization, at least a procedure of notification. This, it is argued, would enable authorities to better control these products and should provide a basis for monitoring the effects of vitamin and mineral supplements on nutrient status of the population. Others suggest that such a procedure would be burdensome, both for manufacturers and authorities, and possible benefits would have to be carefully considered and weighed in future discussions.

Epilogue

48. The Working Group offers this discussion paper to the Committee for their consideration. We have tried to include a wide range of issues and opinions surrounding consideration of guidelines for vitamin and mineral supplements. However, we anticipate that additional opinions and issues will surface during Committee discussions. If this is the case, this paper will have fulfilled its purpose by helping to bring out all the issues.