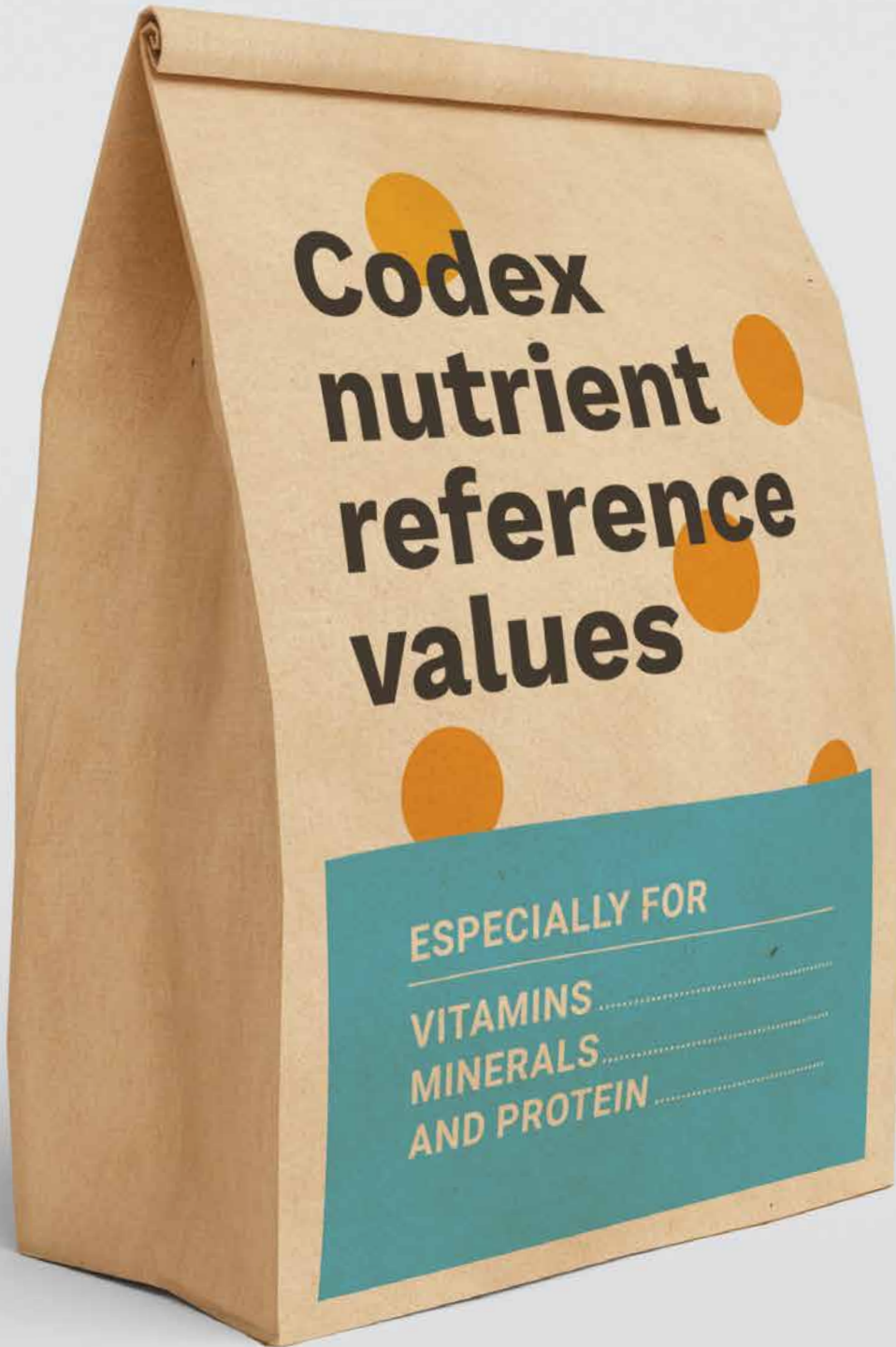




Food and Agriculture
Organization of the
United Nations



World Health
Organization





Codex nutrient reference values

ESPECIALLY FOR

VITAMINS

MINERALS

AND PROTEIN

By Janine Lewis

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Sugars Brown
Serving Size 100g/3.5oz

Amount	% Daily Value
Calories 377	
Calories from Fat 0	
Total Fat 0 g	0%
Saturated Fat 0 g	0%
Trans Fat 0 g	

rition Facts

es
100g/3.5oz
% Daily Value

6	
m Fat 3	
5 g	1%
ed Fat 0 g	0%
t 0 g	
0 mg	0%
	1%
14 g	5%
	10%

tion Facts

ze 100g/3.5oz
% D
ies 580
ies from Fat 440
Fat 51 g

Acronyms

AI	adequate intake
AMDR	acceptable macronutrient distribution range
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CAC	Codex Alimentarius Commission
CCFL	Codex Committee on Food Labelling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
DFE	dietary folate equivalents
DIRV	daily intake reference values
EFSA	European Food Safety Authority
EWG	electronic working groups
FAO	Food and Agriculture Organization of the United Nations
FOPL	front-of-pack labelling
INL98	Individual Nutrient Level 98
IOM	Institute of Medicine
IZiNCG	International Zinc Nutrition Consultative Group
NCHS	National Center for Health Statistics
NHMRC/MOH	National Health and Medical Research Council and New Zealand Ministry of Health
NIHN	National Institute of Health and Nutrition
Nordic	Nordic Council of Ministers
NRVs	nutrient reference values
NRVs–NCD	nutrient reference values – non-communicable diseases
NRVs-R	nutrient reference values – requirements
PRI	population reference intake
PWG	physical working group
RASBs	recognized authoritative scientific bodies
RAE	retinol activity equivalents
RDAs	recommended daily allowance
RE	retinol equivalents
RNI	reference nutrient intake
SCF	scientific committee on food
UL	upper level of intake
UNICEF	United Nations International Children’s Emergency Fund
UNU	United Nations University
WHO	World Health Organization



4.2 Principles for determining mandatory requirements

Principles for the mandatory (core) composition of products for young children:

Evidence to support:

1. Identification of nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale; and/or
2. Contribution of alternative attributes of key nutrients from other foods where such nutrients are key contributors to the diet of young children; and/or
3. The nutritional quality and integrity of product to ensure nutritional safety.

Foreword



The review of the 1993 Nutrient Reference Values (NRVs) for the essential nutrients protein, vitamins and minerals for labelling purposes in the *Codex Guideline on Nutrition Labelling* including the elaboration of the “General Principles for Establishing Nutrient Reference Values for the General Population”, was a major project of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). While the guidelines as such fall within the competence of the Codex Committee on Food Labelling, the nutritional, scientific issues such as the elaboration of NRVs are dealt with by CCFNSDU.

CCNFSDU worked on this project for more than ten years. At its 25th session in 2003 CCFNSDU started to discuss updating the existing NRVs for protein, vitamins and minerals and the elaboration of additional NRVs. The Codex Alimentarius Commission (CAC) approved this new work in 2008. During the following years this task was a major part of the work of CCFNSDU. It was a very complex, technical and therefore demanding project which required an extensive evaluation of the scientific basis. During the process it was agreed to use the term NRVs-R (requirement) for the essential nutrients, protein, vitamins and minerals. It was also decided to focus as a first step on the NRVs-R for the general population and to follow a step-wise approach in revising and elaborating NRVs-R.

Physical and electronic working groups prepared excellent documents as a basis for the discussions at the sessions of CCFNSDU. Much appreciated support was provided by the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) with their report “Review of Existing Daily Vitamin and Mineral Intake Reference Values” in 2011 as requested by CCFNSDU. The project could finally be completed at the 38th session of CCFNSDU in 2016 with regard to the NRVs-R for the general population. The work on NRVs-R for vitamins and minerals for older infants and young children is still ongoing.

It may seem challenging, especially for those not directly involved in the work, to understand how the new NRVs-R were derived, why this important project took so many years and just how many documents were produced in that period. This publication clearly describes the process and brings together all relevant information and aspects of this work including the scientific basis and further background information. It helps to better understand the project and its results.

Pia Noble

Former Head of Division of Special Foods, Food Supplements, Food Additives,
Federal Ministry of Food and Agriculture of Germany
Chairperson of CCFNSDU (2010-2017)

Acknowledgements

The review of the Codex nutrient reference values for protein, 13 vitamins and 6 minerals in the Codex guidelines for nutrition labelling was accomplished over several years through the sustained and thoughtful contributions of many government and non-government delegations, FAO and WHO, and the Chair of the Codex Committee on Nutrition and Foods for Special Dietary Uses. In particular, FAO and WHO are acknowledged for their timely assistance in compiling a global reference of nutrient intake values from around the world.

The Codex Alimentarius Secretariat acknowledges the leadership and contribution of Verna Carolissen, Food Standards Officer with responsibility for the Codex Committee on Nutrition and Foods for Special Dietary Uses, in developing the original concept for this publication.

About the author



Janine Lewis is Principal Nutritionist at Food Standards Australia New Zealand and a highly experienced food regulator whose career in national and international regulation spans 25 years.

Janine leads a small team developing nutrition-based regulations including for addition of vitamins, minerals and other nutritive substances to food, nutrient reference values for labelling purposes, and special purpose foods such as infant formula products and foods for special medical purposes.

Janine also served as leader of the Australian delegation to the Codex Committee on Nutrition and Foods for Special Dietary Uses for 17 years, 1998 – 2016. During that time, she led two projects developing nutritional risk analysis principles applicable to the Committee (2009), and a review of Codex nutrient reference values for vitamins, minerals and protein for labelling purposes (2010 – 2015). Janine previously contributed to *Guidelines on food fortification with micronutrients* (WHO/FAO, 2006) and subsequently spent two short secondments assisting WHO's early development of a system for provision of scientific nutrition advice.

Nutrition facts

per Serving*

per 1/5 Packet

32

0.5

3.2

2.3

1.4

1.3

0.1

0.5

Introduction

Nutrient reference values (NRVs) are a set of values used in nutrition labelling derived from authoritative recommendations for daily nutrient intake. These recommendations are based on best available scientific knowledge of the daily amount of energy or nutrient needed for good health. NRVs do not appear on the label but they are used in nutrition labelling to show the contribution to healthy nutrient intake of the nutrients in a portion of food.

This booklet documents the process and decisions involved in reviewing the Codex NRVs for vitamins, minerals and protein; as such, it provides a valuable record of many years of novel and complex technical work.

Chapter 2 describes nutrition labelling from its inception in the 1940s through to work that has taken place in Codex over the last 40 years. **Chapter 3** discusses specific Codex texts related to nutrition labelling and how “nutrient reference values – requirements” (NRVs-R) are used to provide meaningful information about a food’s nutrient content for consumers. **Chapter 4** explains the interaction between the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and the Codex Committee on Food Labelling (CCFL), and the process adopted in the review for NRVs over the last 25 years. **Chapters 5 and 6** consider in detail how Codex NRVs were derived. They include background on data sources, terminology and interaction with the Codex parent bodies, FAO and WHO. **Chapter 7** examines the impact of NRV-R updates on food manufacturers, consumers and food trade. **Chapter 8** points readers to an information document on the derivation of NRVs, while **Chapter 9** provides some reflections on the past and future development of NRVs-R.

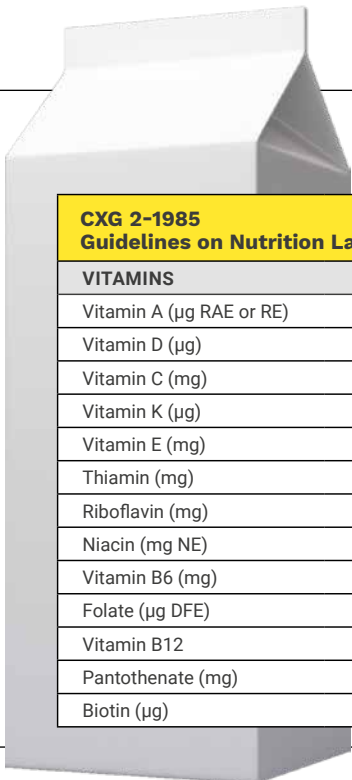
The booklet is intended for the wider Codex community, national and regional food regulators, nutrition policymakers, health professionals and educators, and interested members of the community. Although possessing a technical background may be an advantage, the non-specialized reader will find all terminology clearly defined and the science behind the work carefully explained.

Figure 1
How nutrient reference values reach a food label

- a.** Governments, FAO/WHO or other recognized scientific bodies **establish values stating how much of a certain nutrient** (e.g. calcium, vitamin C) **is needed per day to stay healthy for the general population.**

These values are called:

reference nutrient intake values



CXG 2-1985 Guidelines on Nutrition Labelling	
VITAMINS	
Vitamin A (µg RAE or RE)	800
Vitamin D (µg)	5-15
Vitamin C (mg)	100
Vitamin K (µg)	60
Vitamin E (mg)	9
Thiamin (mg)	1.2
Riboflavin (mg)	1.2
Niacin (mg NE)	15
Vitamin B6 (mg)	1.3
Folate (µg DFE)	400
Vitamin B12	2.4
Pantothenate (mg)	5
Biotin (µg)	30

- b.** The values are used for many purposes:

- establishing **nutrient reference values (NRVs-R, NRVs-NCD)**

- and other uses too:

- Monitor nutrition programmes
- Assess food supplies and nutritional needs
- Plan development activities
- Guide nutrition education programmes

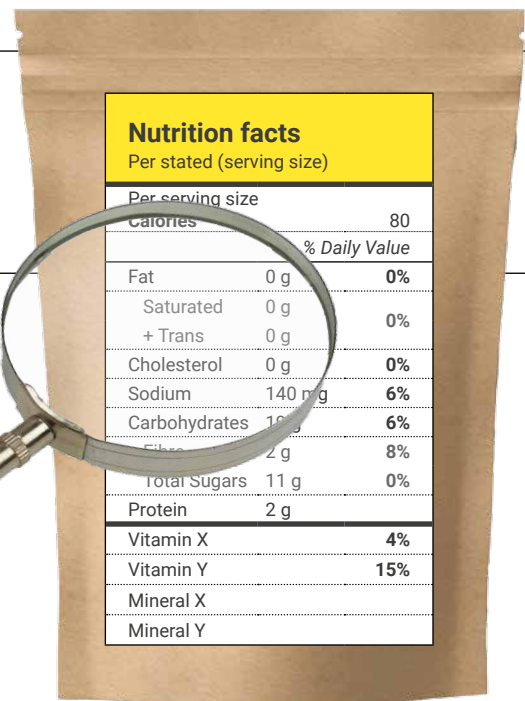
- c.** Food producers may use the NRVs to produce their **nutrition label**

- d.** **Nutrition labelling helps all of us:**

make individual food choices **1**

compare different food products **2**

know how much we eat **3**



Nutrition facts		
Per stated (serving size)		
Per serving size		
Calories		80
		% Daily Value
Fat	0 g	0%
Saturated	0 g	0%
+ Trans	0 g	
Cholesterol	0 g	0%
Sodium	140 mg	6%
Carbohydrates	10 g	6%
Fiber	2 g	8%
Total Sugars	11 g	0%
Protein	2 g	
Vitamin X		4%
Vitamin Y		15%
Mineral X		
Mineral Y		

What is nutrition labelling?

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Nutrition labelling provides label information about a food's key nutrient content to inform consumers about the nutritional quality of the foods they purchase. Food regulators around the world establish nutrition labelling regulations that apply in their jurisdiction. They do this by taking account of Codex guidance and determining the most appropriate information to appear on the label in terms of public health needs, consumer understanding and food industry capacity.

The choice of nutrients includes: energy, macronutrients such as protein, fat and carbohydrate and their components; sodium and potassium; and vitamins and minerals. Certain nutrients may be always declared because of their nutritional significance, whereas other nutrients may be declared at a manufacturer's discretion or as a condition of making a nutrient content label claim.

Nutrition labelling is presented in a standardized format on pre-packaged foods to enable consumers to find the information consistently across products. However, the specific format and information details vary according to national needs.

A common format is a matrix table with a list of nutrients in the first column and their respective amounts in the food shown in one or more columns across the table. Nutrient amounts may be shown in metric units and/or as a percentage of an NRV in one or more quantities of food such as 100 g or 100 ml, or a described portion size.

NRVs are derived from recommendations for healthy nutrient requirements and can be used in nutrition labelling to convert nutrient amounts expressed in metric units e.g. grams, into

a percentage of these recommendations. Because NRVs have been established for almost all nutrients, declaration as “% NRVs” can provide a general profile of a food’s nutritional contribution. Interpreting a food’s nutrient content in this way informs consumers more easily about the contribution of foods to healthy dietary intake.

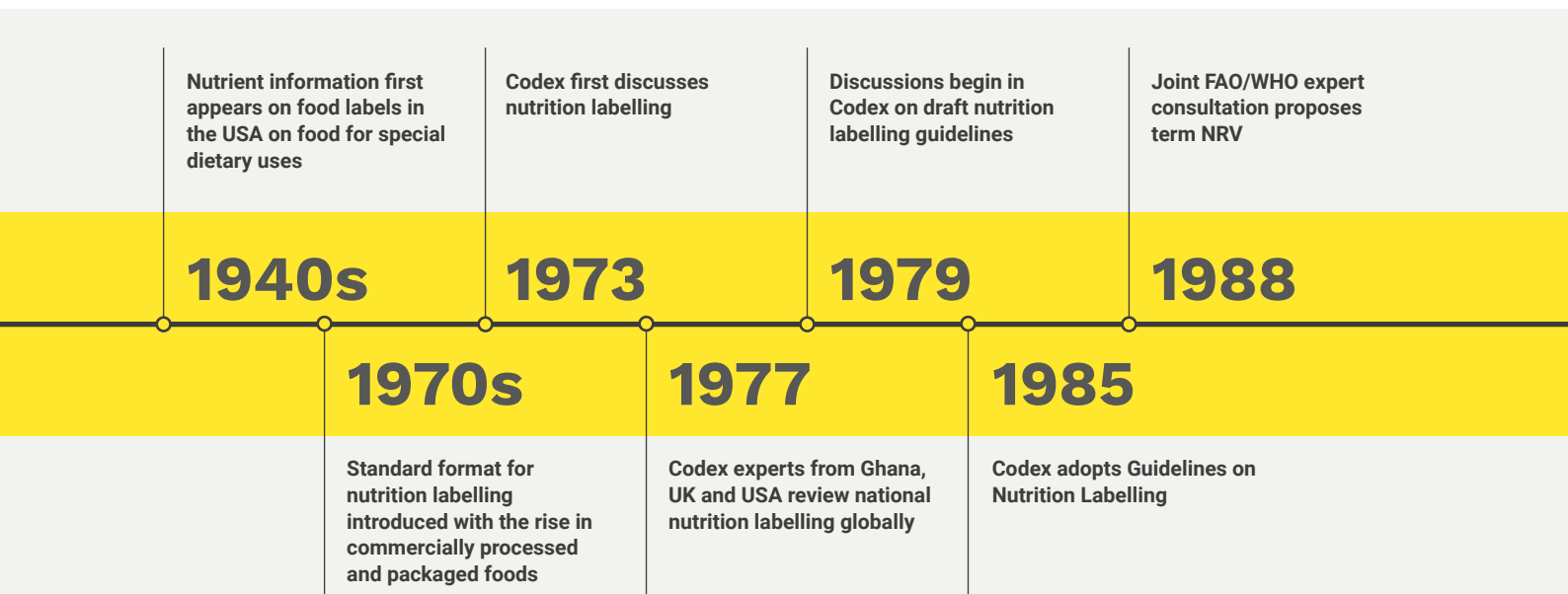
Each nutrient has a single NRV that represents the probable healthy nutrient intake of the general population. Values are either encouraged to be met or discouraged from being exceeded. As such, they fall into two groups of nutrients: protein, vitamins and minerals; and fat, carbohydrate and sodium/salt. Codex NRVs are also used as a reference for minimum conditions for protein, vitamin and mineral content claims.

2.1 History of nutrition labelling

The nutrient content of food first appeared on food labels in the 1940s in the United States of America on food for special dietary use for nutrients that were the subject of a label claim. On some foods, a claim about a vitamin or mineral required declaration of its content and also its expression as a percentage of “minimum daily requirement.”

Today’s concept of nutrition labelling in a standardized format was introduced in the United States of America in the early 1970s when commercially processed and packaged foods became more prevalent on the market. Consumer demand for more information about the

Figure 2
Timeline: history of nutrition labelling



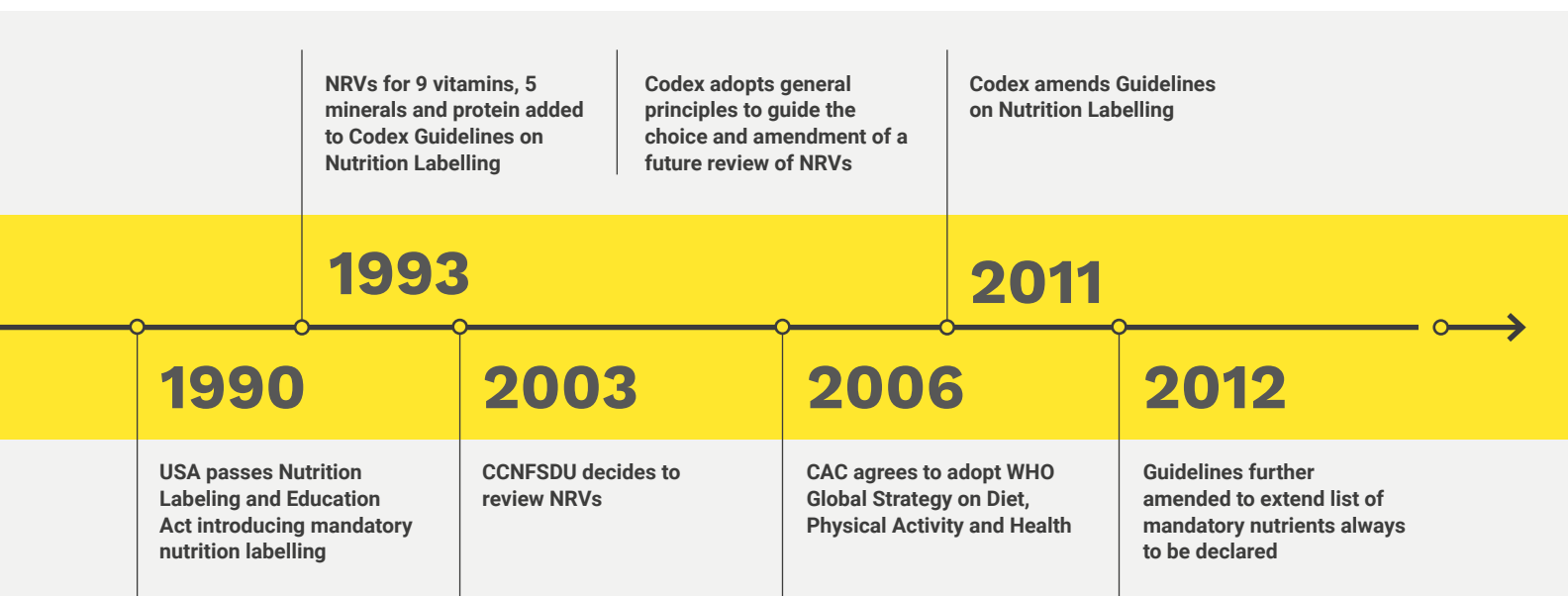
nutritional composition of foods increased as more packaged food replaced home-prepared foods, and also as public messages began highlighting the importance of diet and health.

At that time, the nutrition label was extended to include a more balanced representation of a food's nutrient content by requiring declaration of energy, macronutrients, five vitamins, two minerals and possibly sodium in addition to any claimed nutrient. Protein and micronutrients were to be expressed as a percentage of a reference nutrient standard prescribed in regulations.

This type of nutrition labelling is often described as voluntary because it is not broadly mandated across the food supply. Manufacturers could either freely choose to use nutrition labelling to inform consumers, or else it was conditional when a voluntary nutrient claim was made.

The United States of America was the first country to introduce mandatory nutrition labelling in 1993 after the passage of Nutrition Labeling and Education Act in 1990.

Various approaches are now used internationally. During WHO's second Global Nutrition Policy Review in 2016–17, 163 countries reported on their actions to promote healthy diets, including dietary guidelines, nutrition labelling and portion size control. The most common types of nutrition labelling of pre-packaged foods and beverages concerned nutrient declaration and list of ingredients. Nutrient declaration was reported by at least 80 percent of countries in the WHO regions of the Americas, Europe and the Western Pacific, but by less than half of the countries in the WHO regions of Africa and South-East Asia. Moreover, an increasing number of countries reported that they are developing and implementing front-of-pack labelling (FOPL) systems, particularly countries in the WHO regions of the Americas, Europe and the Western Pacific (WHO, 2018).



2.1.1 Codex Alimentarius

Codex first discussed nutrition labelling in 1973 (ALINORM 74/22). It was acknowledged that practical experience with nutrition labelling on a wide range of foods was globally limited and consumer education would be required. Twin objectives for a uniform system of nutrition labelling were anticipated to provide meaningful information to consumers and to substantiate manufacturers' nutrient claims.

In 1977, three experts from Ghana, the United Kingdom of Great Britain and Northern Ireland, and the United States of America were appointed to review national nutrition labelling regulation around the world, and thence to elaborate draft Codex guidelines on nutrition labelling. An international harmonized approach was considered not only to provide guidance but also to allay potential impediments to trade, given the diversity of national capacity to devise and support nutrition labelling regulation.

Discussion first began on the draft nutrition labelling guidelines section by section in 1979 and, after several iterations over the next few years, the Guidelines on Nutrition Labelling were adopted in 1985.

The Codex Guidelines were amended in 2011 to revise the basis of nutrition labelling on pre-packaged foods from voluntary to mandatory (CCFL, 2011), and again a year later to extend the list of nutrients always to be declared (CCFL, 2012). These changes were in response to Codex's action plan to implement the 2006 WHO Global Strategy on Diet, Physical Activity and Health (CAC, 2006).

Recommended intakes in the Guidelines on Nutrition Labelling

The contribution of foods to good nutrition was originally considered an optional part of nutrition labelling that could be included for populations who understood the concept of nutritional requirement. However, differing views were held when a specific list of reference nutrient values for optional use in nutrient declaration was proposed that discussed the advantages. One view held that percentage of a reference value was the most meaningful way of expressing nutrition information numerically for the consumer. Another view held that nutrient declaration should first relate to the food and not to factors concerning the total diet, as nutritional references were not applicable on a worldwide basis nor understood by the consumer. Moreover, it was not feasible to relate a quantitative declaration of nutrients to RDAs¹ as this was not understood by the consumer.

¹ Not explained in available Codex documentation, but most probably refers to the term in United States of America food regulations at the time: recommended *daily* allowance.

Over time, more consideration was given to providing international guidance. By 1983, the following footnote was included.

3.2.4.1 Only vitamins and minerals for which recommended intakes have been established and/or which are of nutritional importance in the country concerned should also be declared.*

* Recommended intakes for certain vitamins and minerals have been established by a number of countries. Recommended intakes have been established by FAO/WHO for vitamins A, D, thiamin, riboflavin, niacin, folic acid, vitamin B12, ascorbic acid, calcium and iron (Handbook on Human Nutritional Requirements 1974, FAO Nutritional Series No. 28; WHO Monograph Series No. 61).

By the time the Guidelines were finalized in 1985, the general reference was replaced by an interim set of values, i.e. RDAs for energy, protein, 10 vitamins and 6 minerals. Most of these values were derived from the United States Recommended Dietary Allowances, ninth edition (National Research Council, 1980) for males aged 23–50 years. Iron appears to be the average of male and female RDAs (10 mg and 18 mg) for the same age range. Reference values for energy, protein and magnesium were sourced from elsewhere.

These interim values had not been thoroughly discussed and were expected to be updated after the following FAO/WHO review of nutrient requirements while also noting that recent FAO/WHO reports had updated requirements for energy, protein, vitamin A, iron, folate and vitamin B12.

Nutrient reference values

The term “nutrient reference value” (NRV) was proposed by a 1988 joint FAO/WHO expert consultation convened in response to the Commission’s request to recommend reference nutrient amounts for food labelling purposes. The term was coined to avoid confusion with the United States of America term RDA and to more clearly indicate to consumers (and the scientific community) that the references served specifically as a uniform standard for ready comparison of the nutrient content of foods and did not relate directly to individual requirements.

NRVs for 9 vitamins, 5 minerals and protein as recommended by the expert consultation were adopted into the Guidelines on Nutrition Labelling in 1993 along with updates to the terminology and footnotes indicating NRVs should be kept under review and also specifying vitamin A conversion factors. **Table 1** shows both sets of reference values and the basis for the 1993 change.

Table 1
Comparison of reference values in the Codex Guidelines on Nutrition Labelling, up to 1993

Nutrient	Reference RDA (1985)	NRV (1993)	NRV Reference (1993)
Energy MJ (kcal)	9.5 (2300)	–	Did not set
Protein g	50	50	FAO/WHO, 1985
Vitamin A µg	1000	800 µg RE	FAO/WHO, 1988
Vitamin D µg	5	5*	No change
Vitamin E mg	10	–	Did not set
Vitamin C mg	60	60	No change
Thiamin mg	1.4	1.4	No change
Riboflavin mg	1.6	1.6	No change
Niacin mg	18	18*	No change
Vitamin B6 mg	2	2	No change
Folacin µg	400	Folic acid 200	FAO/WHO, 1988
Vitamin B12 µg	3	1	FAO/WHO, 1988
Calcium mg	800	800	No change
Phosphorus mg	800	–	Did not set
Iron mg	14	14	FAO/WHO, 1988
Magnesium mg	300	300	No change
Zinc mg	15	15	No change
Iodine µg	150	150*	No change
Copper	–	Value to be established	Did not set
Selenium	–	Value to be established	Did not set

* Nutrient Reference Values for vitamin D, niacin and iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.4.1 of the Codex Guidelines on Nutrition Labelling.



The following general principles to guide the choice and amendment of a future review of NRVs were also adopted in 1993.

-
1. While establishing Nutrient Reference Values (NRVs), the Principles for Nutrition Labelling as contained in the Codex Guidelines on Nutrition Labelling should be followed.
 2. The primary purpose of NRVs is to give meaningful and not misleading information to the consumer.
 3. The composition of the list should be carefully considered and justified in terms of the consumers' needs.
 4. A list of NRVs for foods targeted to the general population should be established. The need to establish NRVs for specific groups such as infants and children should also be considered.
 5. NRVs should be based as far as possible on nutrient intakes recommended by FAO and/or WHO. The source of values should be indicated and justified.
-





Codex nutrition labelling today

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Codex nutrition labelling guidelines assist food regulators around the world to develop a standardized approach to the provision of nutrition information on food labels, and to establish the conditions for making nutrition and health claims. As such, these guidelines also provide flexibility for regulators to select the most appropriate approach for their population. The application of these guidelines to food labelling is intended to provide consumers with information to enable wise food purchasing decisions; also for label claims to be based on sound nutrition principles in support of national nutrition policies to the benefit public health.

The two Codex nutrition labelling guidelines are:

1. Guidelines on Nutrition Labelling (CXG 2-1985)
2. Guidelines for Use of Nutrition and Health Claims (CXG 23-1997).

Nutrition labelling provides consumers with information about the key nutrient content of foods in a standardized format. Codex regards nutrients as any substance normally consumed as a constituent of food:

- a. which provides energy; or
- b. which is needed for growth, development and maintenance of life; or
- c. a deficit of which will cause characteristic biochemical or physiological changes to occur.

Nutrients include energy, macronutrients such as protein, fat and carbohydrate, and vitamins and minerals.

Nutrients and their amounts listed in the nutrition label may be always declared or declared voluntarily or as a condition of making a nutrition and/or health claim. Codex nutrition labelling requires the mandatory declaration of energy, protein, fat, saturated fat, available carbohydrate, total sugars and sodium or salt (as sodium equivalents). Vitamins and minerals are declared either voluntarily or due to a label claim; however, national regulation may also require key nutrients to be declared because of their nutritional importance.

Codex nutrition labelling provides a high degree of flexibility for declaration of nutrient content in order to be meaningful for consumers. Nutrient amounts can be declared in metric units of grams, milligrams or micrograms as appropriate and/or as a percentage of established NRVs. When nutrition labelling is widely applied, consumers can directly compare the nutrient content of pre-packaged foods.

However, the nutritional significance of a food is difficult to convey when nutrient content is given in metric units alone and without interpretive information. The option to express nutrient content as a percentage of established NRVs instead of, or in addition to, metric units has the advantage of informing consumers about the contribution of individual food products to daily nutritional requirements. However, there is no meaningful way to relate a food's declared nutrient content to an individual's nutritional requirements; nor should use of such percentage information lead consumers to believe otherwise.



3.1

Codex nutrient reference values (NRVs)

Nutrient reference values (NRVs) are defined today in the Codex Guidelines on Nutrition Labelling as:

- a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims.

Two types of NRVs are further defined:

- Nutrient reference values – requirements (NRVs-R), which refer to NRVs that are based on levels of nutrients associated with nutrient requirements. NRVs-R are established for vitamins, minerals and protein.
- Nutrient reference values – non-communicable diseases (NRVs-NCD), which refer to NRVs that are based on levels of nutrients associated with the reduction in the risk of diet-related non-communicable diseases not including nutrient deficiency diseases or disorders. To date, NRVs-NCD have been established for saturated fat, sodium and potassium.



The **levels of nutrients** in both definitions refer to daily intakes of nutrients from food that are associated with the stated outcomes. The NRVs-NCD for saturated fat and sodium are given as intake levels that should not be exceeded; and for potassium, as an intake level to achieve. Both types of NRVs apply to the general population, which, in this context, excludes infants and young children.

NRVs have different applications in the two Codex nutrition labelling guidelines. The Guidelines on Nutrition Labelling contains the list of nutrients and their NRVs, sets out the use of NRVs in nutrient declaration; and documents the principles for establishing NRVs. The Guidelines for Use of Nutrition and Health Claims sets minimum conditions for nutrition claims about protein, vitamins and minerals as a percentage of the NRVs-R.

As the underpinning principles for the two types of NRVs differ and are drawn from different data sets, this publication focuses on NRVs-R for the essential nutrients protein, vitamins and minerals.

3.1.1 Use of Codex nutrient reference values – requirements (NRVs-R) in nutrition labelling

Declaration of nutrient content

NRVs-R are used to convert a nutrient amount in metric units into a percentage of daily requirement. **Table 2** shows the amounts of three nutrients in metric units in a unit quantity of 100 g and as a percentage of their respective NRVs-R in 100 g and 150 g servings of food. Because space on a food label is often at a premium, nutrition labelling does not show the actual NRVs-R.

Table 2
Example of three nutrients in metric units and as a percentage of their respective NRVs-R in servings of food

Nutrient	Amount/100 g	NRV-R	% NRV/100 g serving	% NRV/150 g serving
Protein	10 g	50 g	20	30
Vitamin C	15 mg	100 mg	15	23
Zinc	2 mg	11 mg	18	27

Conditions for nutrient content claims

Minimum conditions for protein, vitamin or mineral content claims are expressed as a percentage of their respective NRVs-R according to the type of food.

For example, for a source of protein claim, a food must contain not less than 10 percent NRV-R in 100 g or serving (g); or for a liquid, not less than 5 percent NRV-R in 100 ml or 100 kcal. For a source of vitamin or mineral claim, a food must contain not less than 15 percent NRV-R in 100 g or serving (g); or for a liquid, not less than 7.5 percent NRV-R in 100 ml or 100 kcal.

Conditions for comparative claims about protein, vitamins or minerals

Minimum conditions for comparative claims between two similar foods about protein, vitamin or mineral content are based on “% NRVs-R”. For comparative claims about protein, the difference in protein content should be at least 25 percent and 5 g (i.e. 10 percent NRV-R). For comparative claims about vitamins or minerals, the difference in vitamin or mineral content should be at least 10 percent of their respective NRVs-R. Thus, for a comparative claim about the calcium content of two similar foods, the difference should be at least 100 mg.





NRV-R review framework

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4.1

Codex committees

Two committees of the Codex Alimentarius Commission are responsible for nutrition and labelling matters: the Codex Committee on Food Labelling (CCFL) and the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). CCFL is responsible for overall maintenance of the nutrition labelling guidelines, including the appropriate use of NRVs in nutrient declaration and nutrient claim conditions. CCNFSDU is responsible for the selection and currency of the NRVs.

In this review, CCNFSDU developed the general principles, and revised and extended the range of NRVs whereas CCFL ensured that the related changes to the guidelines in support of these values were appropriately made. All CCNFSDU recommendations for text-based amendments to the Guidelines on Nutrition Labelling (i.e. revised definitions, editorial amendments, and annexes) were referred to CCFL for endorsement before being referred to the Commission for adoption.

4.2

Review framework

Reference values for vitamins, minerals and protein were included in the original Codex Guidelines on Nutrition Labelling in 1985 and subsequently updated in 1993 with the intention of keeping them under review. The most recent review of these values established general principles and introduced several definitions as well as updating and extending the reference values.

CCNFSDU decided to review NRVs in 2003 (called NRVs-R from 2012 to differentiate from NRV-NCD). In 2004, electronic working groups (EWG) began work between sessions to plan the approach and formulate recommendations for consideration by the plenary. Delegation leaders from South Africa, the Republic of Korea, and Australia successively led the project.

An initial consideration was whether the review should be conducted by FAO/WHO (as previously in 1988) or by CCNFSDU. Because *Vitamin and Mineral Requirements in Human Nutrition* (WHO/FAO, 2004) had recently become available as a reference source, the review of NRVs for labelling purposes was regarded as a risk management activity and therefore the responsibility of Codex.

CCNFSDU developed a project plan in 2007. General principles for NRVs for vitamins and minerals were developed in 2010 to ensure consistency of approach into the future. These general principles set out key parameters to guide selection of appropriate data sources, and of their candidate values. That same year, FAO/WHO were requested to provide an overview of the global range of adult vitamin and mineral intake reference values and their basis from national reference sources published after 1988. The parent organizations were also requested to indicate the extent of scientific research into individual vitamins and minerals since 1998 in order to assist evaluation of candidate values based on evidence assessed at different points in time.




Chapter 5 gives further details of these processes and outcomes.

The Committee then considered 26 draft revised and new NRVs-R for vitamins and minerals, with associated footnotes. These NRVs-R were first proposed in 2009 and progressively finalized in the five years 2012–16. The need to review the NRV-R for protein was added to the list in 2012.

The 27 draft revised and new NRVs-R were sorted into manageable groups for assessment in line with the general principles. Starting in 2012, two consultation papers were annually circulated to EWG members for comment. These papers set out the scientific details of shortlisted candidate values as a possible basis for each NRV-R under consideration. After considering the comments and preferences for particular candidate values, the EWG Chair drafted the rationale and recommendations to the Committee on the draft proposed and new NRVs-R, together with related conversion factors and footnotes.

The general principles guided that FAO/WHO source documents were to be considered first as they were international in scope and useful in facilitating harmonization. Thereafter, other agreed reference sources from national or regional publications could be consulted. The initial priority for review of individual NRVs-R was adjusted mid-term to allow for consideration of the range of European Food Safety Authority (EFSA) draft and/or finalized dietary reference values developed in 2013–16.

 **Chapter 6** gives further details of these processes and outcomes.





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Derivation of Codex nutrient reference values

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5.1

Project document

In order to advance the work through Codex's step procedure, a project document was finalized in 2007 (CCNFSDU, 2007).

The project document outlined the proposed scope and stepwise approach to the work.

1. Develop general principles for establishment of NRVs for vitamins and minerals for the general population.
2. Review all available reference values and their scientific basis by the principles agreed upon and, if appropriate, update and extend the current list of vitamin and mineral NRVs in the Guidelines on Nutrition Labelling.

3. Establish relevant principles for NRVs for individuals of from 6 months to 36 months of age, using as a basis the principles for NRVs for the general population and modifying them as appropriate.
4. Establish NRVs for this age group.

Scientific advice from FAO/WHO was considered to be identified at a later stage.

5.2

Reference Nutrient Intake Values

Many composite terms are used around the world to describe the daily nutrient intakes required to support human health throughout the life cycle. These terms are usually a combination of two or more key descriptors:

- recommended/reference;
- nutrient/nutritional/dietary;
- allowance/requirement/intake/value;
- daily;
- population.

“Reference nutrient intake value” is the term used in the Annex to the Codex Guidelines on Nutrition Labelling.

Reference nutrient intake values are established by international, regional or national scientific or government agencies based on careful consideration of best available scientific evidence of nutrient requirements from human and animal studies. Factors in the local food supply that may affect the amounts of nutrients absorbed from food are also taken into account. Reference nutrient intake values are established for all age/sex groups across the life cycle and, depending on the remit of the agency, are directed to either national, regional or global populations. They have several important uses that include development of food and nutrition policy, and assessment of nutritional adequacy of national food supplies and dietary guidelines. They are also used for dietary planning for communities such as the military, residential institutions, and schools. Nutrition labelling and food fortification are other important uses.

Reference nutrient intake values for protein, vitamins and minerals are established on the basis of nutritional adequacy, whereas those for dietary energy intakes are established according to healthy body weights at various levels of physical activity. Reference nutrient intake values associated with a decreased risk of non-communicable disease have more recently been evaluated by WHO and some other agencies for carbohydrates including sugars, types of fats, sodium and potassium.

Despite often having a common evidence base, reference nutrient intake values established by various agencies differ for several reasons. For example, the evidence may be considered at different times during the evolution of the evidence base, or scientists may place a different emphasis on certain evidence, the body weights of relevant populations, or dietary factors may differ, etc. Because it is a costly and timely exercise, very few countries have developed their own reference nutrient intake values from a primary evaluation of the evidence. Some countries wholly or partially select or adapt their national reference nutrient intake values from other well-documented reference sources from WHO and/or FAO, Canada, the United States of America or the European Union.

5.3

Codex nutrient reference values

It is neither possible nor appropriate to use reference nutrient intake values set throughout the life cycle for nutrition labelling purposes. Therefore, a process was needed to guide selection of one reference nutrient intake value that could provide an NRV to represent a healthy nutrient intake for the general population for use in nutrition labelling.

Determination of NRVs in one jurisdiction is a simpler process as only one set of reference nutrient intake values is usually required. However, the Codex process required assessment of reference nutrient intake values from several publications, leading to the final selection of one NRV for each nutrient in accordance with the following set of general principles.

5.3.1 General principles

The general principles developed 2004–2010 provided the framework for a review of the 1993 NRVs for vitamins and minerals for the general population.

A report from UNU/FAO/WHO/UNICEF (2007) titled *International Harmonization of Approaches for Developing Nutrient-Based Dietary Standards* guided the choice of terminology for particular reference nutrient intake values.

The report recommended new terminology for use by all countries that established nutrient intake dietary standards (i.e. reference nutrient intake values) derived from primary data. Over time, adoption of this new terminology was envisaged to replace the many names in use for nutrient-based dietary standards. This was intended to avoid confusion over the meaning and use of multiple acronyms for the same concept.

The general principles shown below were annexed to the Codex Guidelines on Nutrition Labelling in 2011. The current version (2017) is given in Appendix 4 with a summary in Box 1.

BOX 1 General principles for establishing nutrient reference values

1. Preamble	<p>These Principles apply to the establishment of Codex nutrient reference values (NRVs) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. Governments are encouraged to use the NRVs, or alternatively, consider the suitability of the general principles below including the level of evidence required, and additional factors specific to a country or region in establishing their own reference values for labelling purposes. For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. In addition, governments may establish reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.</p>
2. Definitions	
2.1	<p>Daily Intake Reference Values (DIRVs) as used in these Principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies (RASBs) that may be considered in establishing an NRV based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or a range), and are applicable to the general population or to a segment of the population (e.g., recommendations for a specified age range).</p>
2.2	<p>Individual Nutrient Level 98 (INL98)* is the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.</p>
2.3	<p>Upper Level of Intake (UL)** is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.</p>

* Different countries may use other terms for this concept for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population reference Intake (PRI).

** Different countries may use other terms for this concept for example, Tolerable Upper Nutrient Intake level (UL) or upper level of safe intake range.

3.	General principles for establishing NRVs
3.1	Selection of Suitable Data Sources to Establish NRVs
3.1.1	Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs.
3.1.2	Relevant daily intake reference values that reflect recent independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.
3.1.3	The daily intake reference values should reflect intake recommendations for the general population.
3.2	Selection of Nutrients and Appropriate Basis for NRVs
3.2.1	The NRVs-R should be based on Individual Nutrient Level 98 (INL98). In cases where there is an absence of an established INL98 for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.
3.2.1.1	The NRVs-R should be based on Individual Nutrient Level 98 (INL98). In cases where there is an absence of an established INL98 for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.
3.2.1.2	The general population NRVs-R should be determined by calculating the mean values for a chosen reference population group older than 36 months. NRVs-R derived by the CCNFSDU are based on the widest applicable age range for each of adult males and females
3.2.1.3	For the purpose of establishing these NRVs-R, the values for pregnant and lactating women should be excluded.
3.3	Consideration of Daily Intake Reference Values for Upper Levels
	The establishment of general population NRVs should also take into account daily intake reference values for upper levels established by FAO/WHO or other recognized authoritative scientific bodies where applicable (e.g., Upper Level of Intake, Acceptable Macronutrient Distribution Range).

Key terms and their definitions

Key terms were progressively defined and key decisions made as needed. Definitions for key terms were created or sourced from various authoritative documents (Table 3).

Table 3
Definitions for key terms

Term	Definition and source
Daily intake reference values (DIRVs)	DIRVs as used in these principles refer to reference nutrient intake values provided by FAO/WHO or recognized authoritative scientific bodies (RASBs) that may be considered in establishing an NRV based on the principles and criteria in Section 3 [of the General Principles]. These values may be expressed in different ways (e.g. as a single value or a range), and are applicable to the general population or to a segment of the population (e.g. recommendations for a specific age range). Defined by CCNFSDU.
Individual nutrient level _{x percentile} (INL _x)	INL is the probability of nutrient adequacy for any single individual; or in population terms, represents nutrient adequacy for a proportion of a population. X represents a particular percentile along a population's nutrient requirement distribution (UNU/FAO/WHO/UNICEF (2007)).
Individual nutrient level ₉₈ (INL98)	The daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of apparently healthy individuals in a specific life stage and sex group. Note this publication has not shown 98 or other percentiles as a subscript for ease of reading. Adapted by CCNFSDU.
Adequate intake (AI)	The observed or experimentally derived intake by a defined population group that appears to sustain health (UNU/FAO/WHO/UNICEF (2007)).
Upper level of intake (UL)	The maximum level of habitual intake from all sources of a nutrient judged to be unlikely to lead to adverse health effects in humans. (Taken from Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses [Codex Alimentarius Commission Procedural Manual]).

Key decisions

Selection of suitable data sources

CCNFSDU's nutritional risk analysis principles had acknowledged FAO and WHO as the primary source of risk assessment advice. On that basis, WHO/FAO (2004) was considered an appropriate and contemporary reference source of candidate reference nutrient intake values, known in the general principles as daily intake reference values (DIRVs). This publication is the second edition of the report from the 1998 joint FAO/WHO expert consultation on vitamin and mineral requirements. The report provided recommended nutrient intakes (reference nutrient intake values) for 13 vitamins and 6 minerals for consideration. FAO/WHO (2006) also updated some information from WHO/FAO (2004) that was particularly relevant to consideration of iron and zinc.

Although FAO/WHO had established recommended nutrient intakes for more vitamins and minerals than the 1993 NRVs, certain other reference sources had established even more reference nutrient intake values for these nutrients. The range of acceptable references was expanded to include publications from recognized authoritative scientific bodies. However, candidate DIRVs from such publications were to be based on recent independent scientific reviews, with higher priority given to evidence evaluated through systematic review.

Selection of nutrients and appropriate basis

The Committee considered whether to adopt individual nutrient level₉₈ (INL98) or individual nutrient level₅₀ (INL50) – the average nutrient requirement – as the basis for vitamin and mineral NRVs. CCNFSDU noted that INL50 was not as widely published as INL98. The use of INL98 as a labelling reference was a more conservative approach than INL50 because it was more likely to exceed the nutrient requirement of the vast majority of a population. Conversely, INL50 was closer to most individuals' requirements, even though some of these would exceed INL50. The Committee determined that INL98 would be more appropriate than INL50 to cover the nutrient needs of the vast majority of a population.

Other types of DIRVs not based on a nutrient requirement distribution, such as adequate intake (AI), were agreed to be considered on a case-by-case basis when an INL98 was not established due to insufficient evidence. Most often, AIs were based on a lesser degree of evidence than INL98 or based on the median dietary intake of a healthy population. However, situations were subsequently encountered where candidate DIRVs from different reference sources were a mix of older INL98 and more recent AIs. As it was observed that the quality of evidence used to establish an INL98 could vary greatly among recognized authoritative scientific bodies, equal consideration of newer AI and older INL98 could be given on a case-by-case basis.

The candidate DIRVs were the average of adult male and female DIRVs from the same reference source. The widest age ranges in WHO/FAO (2004) were for men aged 19–65 years, and for women aged 19–50 years.

Consideration of upper levels

The Committee included a principle to compare candidate DIRVs with relevant upper levels of intake (ULs) as an additional safety measure. As an adult UL always exceeds its respective INL98, ULs for younger age groups were considered appropriate for comparison. **Table 4** shows those selected were for 1–3-year-olds and 4–6-year-olds (or 4–8-year-olds) from the same reference sources as the INL98.

Table 4
ULs for young children used to compare with DIRV

	UL 1–3 / 4–8 years; IOM (2006)	UL 1–3 / 4–6 years; SCF/EFSA (2006)	NOAEL** 1–3 / 4–8 years; IZiNCG (2004)
Vitamins			
Vitamin A (µg)	600 / 900 (retinol only)	800 / 1 100 (retinol only)	
Vitamin C (mg)	400 / 650	ND / ND	
Vitamin D (µg)	50 / 50	50 / 50	
Vitamin E (mg)	200* / 300*	100 / 120	
Vitamin K (µg)	ND / ND	ND / ND	
Thiamin (mg)	ND / ND	ND / ND	
Riboflavin (mg)	ND / ND	ND / ND	
Niacin (mg)	10* / 15 *	2 / 3 (nicotinic acid)	
Vitamin B ₆ (mg)	30 / 40	5 / 7	
Vitamin B ₁₂ (µg)	ND / ND	ND / ND	
Folate (µg)	300* / 400*	200* / 300*	
Biotin(µg)	ND / ND	ND / ND	
Pantothenate (mg)	ND / ND	ND / ND	
Minerals			
Calcium (g)	2.5 / 2.5	ND / ND	
Chromium (µg)	ND / ND	ND / ND	
Copper (µg)	1000 / 3000	1000 / 2000	
Fluoride (mg)	1.3 / 2.2	1.5 / 2.5	
Iodine (µg)	200 / 300	200 / 250	
Iron (mg) (unknown % absorption)	40 / 40	ND / ND	
Magnesium (mg)	65* / 110*	ND / 250*	
Manganese (mg)	2 / 3	ND / ND	
Molybdenum (µg)	300 / 600	100 / 200	
Phosphorus (g)	3.0 / 3.0	ND / ND	
Selenium (µg)	90 / 150	60 / 90	
Zinc (mg) (unknown % absorption)	7 / 12	7 / 10	8 / 14
Chloride (g)	2.3 / 2.9	ND / ND	

* Supplemental or synthetic forms only.

** No observed adverse effect level.

5.3.2 Preparatory research

As the general principles were nearing completion, CCNFSDU (2010) turned its attention to the draft revised and new NRV-Rs for vitamins and minerals initially presented in 2009 (CCNFSDU, 2009). The 2009 list proposed to extend the range of NRVs in the Guidelines on Nutrition Labelling by 4 new vitamins to 13, and by 6 new minerals to 13, to 26 in total.

In 2010, a physical working group (PWG) considered the candidate DIRVs for the 26 nutrients: 13 vitamins and 6 minerals from WHO/FAO (2004) and 7 additional minerals from United States of America dietary reference intakes (IOM, 1997, 2001, 2005). However no consensus was reached on the suitability of these DIRVs because detailed supporting data about their derivation were not presented. To assist the process, CCNFSDU requested FAO/WHO to conduct a worldwide review of international and national DIRVs published after 1998 and to report the findings the following year. The year 1998 was chosen because it corresponded to the year the joint expert meeting deliberated on recommended nutrient intakes reported in WHO/FAO (2004).

Request to WHO/FAO (reproduced)

1. WHO/FAO are requested to provide a report to 33rd session of CCNFSDU, 2011 that details the results of a review of existing daily vitamin and mineral intake reference values and their basis as outlined below for an apparently healthy population of adult males (preferably aged 19–65 years) and adult females (preferably aged 19–50 years). The report, through the presentation of information in tables, should provide a comparison of nutrient recommendations from recognized authoritative scientific bodies and from WHO/FAO. This information should be taken from data sources published after 1998 that reflect the Committee's second draft General Principle for selection of data sources i.e. relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO. The 26 vitamins and minerals, plus sodium and potassium are listed in the Table below.

The details should include, where relevant and available:

- The values themselves
- Applicable age ranges
- Physiological endpoints used to establish the INL50 or similar, or other measures such as AI and the reason for the choice
- Method of calculation of INL98 or similar from INL50 or similar including coefficients of variation
- Reference body weights and basis for extrapolation methods if used
- Determination of or assumptions about dietary bioavailabilities of the vitamin or mineral

- Conversion factors applied to provitamins, isomers or other relevant nutrients to units of equivalents such as niacin equivalents
 - Year that scientific evaluation was conducted
 - Basis for the value i.e., primary evaluation or derivation from other countries' values.
2. WHO/FAO are also requested to provide an estimate to 33rd session of CCNFSDU, 2011 of the extent of the change in the scientific evidence base since 1998 for the 28 vitamins and minerals, sodium and potassium listed in the Table below. It is anticipated that an estimate could be done by a literature search on relevant scientific data bases using appropriate inclusion and exclusion criteria and counting the number of papers published since 1998. The report would document, for each vitamin and mineral, the number of papers found and the search strategy employed.

Vitamins and minerals requested

Vitamins	Minerals
Vitamin A	Calcium
Vitamin D	Magnesium
Vitamin E	Iodine
Vitamin K	Iron
Vitamin C	Zinc
Thiamin	Selenium
Riboflavin	Copper
Niacin	Chloride
Vitamin B6	Chromium
Folate	Fluoride
Vitamin B12	Manganese
Pantothenate	Molybdenum
Biotin	Phosphorus
	Sodium
	Potassium

Report from FAO/WHO

In response to the request, FAO/WHO presented their report *Review of Existing Daily Vitamin and Mineral Intake Reference Values* (FAO/WHO, 2011) to CCNFSDU that provided:

- a comparison of DIRVs from recognized authoritative scientific bodies and from FAO/WHO published in reference sources after 1998;
- an estimate of the extent of the change in the scientific evidence base related to nutrient requirement for the nutrients of interest.

FAO/WHO used several methods to gather the information. Data were retrieved from available databases and published documents, followed by examination of the original references for DIRVs. National authorities were contacted through FAO/WHO regional and country offices, and a call for data was issued through the Codex Secretariat. A spreadsheet showing all the collected information from 55 countries was made available on the Codex website (no longer available) for reference.

The proportion of 55 countries having a DIRV for a particular nutrient was 96 percent for vitamins A and C, thiamin, riboflavin, calcium and iron; and 80–95 percent for niacin, folate, vitamins B6, B12, D and E, iodine, magnesium, phosphorus, selenium, copper and zinc. DIRVs for the remaining 3 vitamins including biotin and pantothenate, and 5 minerals (excluding sodium and potassium) were found in reference sources from only 31–54 percent of countries.

The report made the important point that a lack of common naming terminology among countries made it difficult to classify the basis for the DIRVs. Different terms were used for the same concept, and the same term was used for different concepts, depending on the country or organization. In order to classify and present the data, terms with varied definitions were categorized into one of three groups as either INL98, AI or unclear. This lack of clear differentiation was to become a practical issue in the review of NRVs-R.

One clear observation was that few national sets of DIRVs were based on a country's primary analysis of scientific data. This was not a surprising finding as such an undertaking is an expensive exercise. The report found that many DIRVs for the same nutrient had the same basis and same value, or were adapted from another country's primary analysis according to relevant parameters. This outcome demonstrated the need to identify the primary sources through application of a working definition of a recognized authoritative scientific body.

For FAO/WHO to gauge the extent of change in the human evidence base for the 28 nutrient DIRVs since 1998, a search of the peer-reviewed scientific manuscripts in the PubMed bibliographic database was conducted. The total numbers of citations of original articles and of randomized control trials were recorded. The results indicated a very wide range of research interest with almost 60 000 scientific papers published about calcium and fewer than 300 papers about pantothenate. Although the report was not specifically limited to research relevant to the DIRV evidence base, it provided guidance on the importance of selecting DIRVs for certain nutrients that were based on the best available data.



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NRVs-R, 2012–2016

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On the basis of the findings of FAO/WHO (2011), CCNFSDU (2012) established an EWG to consider all 26 draft NRVs-R initially presented in 2009, 19 of which came from WHO/FAO (2004) and a further 7 from the United States Institute of Medicine (IOM, 1997, 2001, 2005) for additional minerals. The review was undertaken according to the previously adopted general principles in two stages. As WHO/FAO (2004) was the primary reference source for 13 vitamins and 4 minerals, the suitability of its DIRVs was assessed with reference to FAO/WHO (2011) and associated spreadsheet. After analysis, CCNFSDU (2012) agreed to 8 revised and 3 new NRVs-R based on WHO/FAO (2004).

CCNFSDU (2013) began to review DIRVs as the basis for the 15 remaining 2009 draft NRVs-R from recognized authoritative scientific bodies (RASBs) as well as from WHO/FAO (2004). A schedule arranging the 2009 NRVs-R into groups over the following three years was drawn up in response to a request by the Codex Executive. The 1993 protein NRV was also included in the review so as to become an NRV-R. In the period 2013–16, EFSA progressively released draft and final opinions on its dietary reference values for individual vitamins and minerals. Therefore, the order of the Codex review was adjusted in line with EFSA's schedule as much as possible to take full advantage of recently derived values.

In 2016, CCNFSDU completed the review of 26 NRVs from 1993 for the general population, by establishing a total of 23 vitamin and mineral NRVs-R and 1 NRV-R for protein; however, NRVs-R for another 3 minerals could not be established. A separate project established new NRVs-NCD rather than NRVs-R for sodium and potassium.

6.1

Phase 1: NRVs-R from FAO/WHO

After the development of the general principles, the Committee returned to considering the suitability of the 2009 draft NRVs-R. The Committee sought to assess how well the 2009 draft NRVs for 13 vitamins and 6 minerals from FAO/WHO (2004) represented the global range of DIRVs. To assist assessment, FAO/WHO was requested to compile a global report of adult DIRVs and their supporting details for 28 vitamins and minerals in use around the world. The report and accompanying spreadsheet (FAO/WHO, 2011) contained adult DIRVs for each nutrient sourced from up to 55 countries (see section 5.3.2).

DIRVs were sometimes given separately for males and females and in different age ranges and increments. To enable comparison for each nutrient, national DIRVs in the spreadsheet were standardized, as needed, by removing sex differences and amalgamating into one age group 19–50 years. These standardized DIRVs were then sorted into INL98, AI and INL98 + AI (+ unclear) groups, and the global median calculated for each group. The combined group was important because FAO/WHO (2011) had noted that, for most vitamins and minerals, the DIRVs from the various countries for a single nutrient were never consistently derived as one type or the other; they were always a mix of INL98 and AI (CCNFSDU, 2012a).

The 2009 draft NRVs-R were compared with their respective three global medians. The difference between the draft NRV-R and global median combined INL + AI was also expressed as a percentage of that median.

Table 5 shows the results for calcium where N is the number of countries contributing a DIRV for calcium. In this case, the 2009 draft revised calcium NRV was 11 percent higher than the global combined median.

Table 5
2009 draft NRV-R for calcium compared with global medians of DIRVs for calcium

2009 draft NRV-R	Median INL98 (N)	Median AI (N)	Median combined INL+ AI (N)	Difference between draft NRV-R and combined median as a % combined median
1 000 mg	885 mg (40)	1 000 mg (10)	900 mg (50)	11% (100/900)

The absolute percentage differences for the 13 vitamins and 6 minerals from FAO/WHO (2004) were sorted into incremental thresholds (> 10 percent; > 15 percent; > 29 percent; > 39 percent) to gauge their potential unsuitability based on the extent of difference with median global values (Table 6).

Table 6
Thresholds for potential unsuitability of vitamins and minerals

Potential thresholds for draft NRVs to be unsuitable	Vitamins and minerals whose DIRVs from WHO/FAO (2004) exceed each threshold
> ±10%	vitamin A, vitamin C, vitamin E, calcium, magnesium, selenium
> ±15%	vitamin A, vitamin C, vitamin E, magnesium, selenium
> ±29%	vitamin A, vitamin C, selenium
> ±39%	vitamin C, selenium
> ±49%	nil

The cutoff for unsuitability was set at < ±15 percent which enabled the WHO/FAO (2004) DIRVs to be used as the basis of draft NRVs-R for 9 vitamins and 2 minerals (including calcium). The 2009 draft NRVs-R for the remaining five vitamins and minerals, plus iron, zinc and vitamin D needed further consideration for the following reasons. The percentage difference for vitamins A, C and E, selenium and magnesium were greater than the cutoff, so other reference sources needed to be consulted; iron and zinc had multiple DIRVs associated with dietary patterns; and the science for vitamin D had been recently updated.

CCNFSDU (2012) agreed 11 NRVs-R comprising 7 revised, 1 unchanged, and 3 new NRVs-R based on WHO/FAO (2004), where the absolute difference was < 15 percent of the global combined median. Conversion factors for niacin equivalents and dietary folate equivalents

were also agreed. Table 7 provides a comparison of the differences between the 1993 NRVs and the NRVs-R in the first group. The 1993 NRVs and reviewed NRVs-R in Table 7 indicate a general trend of B group vitamins revising slightly downward except for folate and vitamin B12, and a slight rise in the calcium NRV-R.

Table 7
1993 NRVs and reviewed NRVs-R, up to 2012

Vitamin or mineral	NRVs (1993)	NRVs-R (2012)
Revised NRV-R		
Thiamine (µg)	1.4	1.2
Riboflavin (µg)	1.6	1.2
Niacin (mg)/(mg NE)	18 (footnote)	15 (no footnote, new table for conversion factors)
Vitamin B6 (mg)	2	1.3
Folic acid (µg) / Folate (µg DFE)	200 (folic acid)	400 (folate) (new table for conversion factors)
Vitamin B12 (µg)	1	2.4
Calcium (mg)	800	1 000
Iodine (µg)	150 (footnote)	150 (no footnote)
New NRV-R		
Pantothenate (mg)		5
Biotin (µg)		30
Vitamin K (µg)		60

6.1.1 Conversion factors for vitamin equivalents

Conversion factors were also considered and revised as needed. The name folic acid was amended to folate, and units of dietary equivalents introduced for niacin (as niacin equivalents [NE]) and folate (as dietary folate equivalents [DFE]) from WHO/FAO (2004). A new table was created in the Guidelines on Nutrition Labelling in the format below. A note was added to indicate that the vitamin equivalents provided supporting information to enable authorities to determine appropriate application of NRVs-R. See Appendix 3 for details.

Vitamin	Dietary Equivalents	
Vitamin name	1 metric unit vitamin equivalents =	1 metric unit of 1 st vitamin form X metric unit of 2 nd vitamin form

6.2

Phase 2: Process for NRVs-R from FAO/WHO and other reference sources

6.2.1 Definition of recognized, authoritative, scientific body

In order to address the remaining 15 draft NRVs-R, attention turned to determining appropriate sources of DIRVs from recognized, authoritative, scientific bodies (RASBs) in accordance with the general principles. It soon became clear that a definition of **recognized, authoritative, scientific body** was needed to enable objective selection of appropriate reference sources. CCFNSDU (2012) agreed the following working definition of **recognized, authoritative, scientific body** (RASB) for use in EWG and Committee deliberations.

For the purposes of establishing Codex nutrient reference values, a recognized authoritative scientific body is an organization supported by a government(s) or competent national and/or regional authorities or FAO and/or WHO that provides independent and transparent* authoritative scientific advice on daily intake reference values upon request, and for which such advice is recognized through its use in the development of policies in one or more countries.

* In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

This working definition was amended by CCFNSDU (2013) by inserting **through primary evaluation of the scientific evidence**:

For the purposes of establishing Codex nutrient reference values, a recognized, authoritative, scientific body other than FAO and/or WHO is an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, authoritative and scientific advice on daily intake reference values **through primary evaluation of the scientific evidence** upon request and for which such advice is recognized through its use in the development of policies in one or more countries.

* In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

To assist future deliberations, AIs including those derived from national or regional dietary intakes were considered to be determined through primary evaluation.

After selecting appropriate RASBs, CCNFSDU (2014) added a second footnote to clarify the meaning of primary evaluation** as follows:

** Primary evaluation involved a review and interpretation of the scientific evidence to develop DIRVs rather than the adoption of advice from another RASB.

Given the importance of this finalized definition, CCNFSDU (2015) agreed to insert it into the Annex to the Guidelines on Nutrition Labelling.

6.2.2 Which RASBs?

The Committee considered several scientific bodies nominated by EWG members with supporting justification in relation to all elements of the RASB definition, that is, an organization:

- supported by one or more competent authorities;
- that provides independent, transparent, authoritative, scientific advice on DIRVs through primary evaluation of the scientific evidence upon request;
- whose advice on DIRVs is recognized through use in policy development in one or more countries.

Table 8 lists the six RASBs from their countries/region proposed as meeting the working definition and accepted by CCNFSDU (2014). Their reference publications of DIRVs were used in addition to WHO/FAO (2004).

Table 8
Entities accepted by CCNFSDU as meeting the working definition of RASB

RASB	Country/region
European Food Safety Authority (EFSA)	European Union
Institute of Medicine (IOM)	Canada and the United States of America
National Health and Medical Research Council and New Zealand Ministry of Health (NHMRC/MOH)	Australia and New Zealand
National Institute of Health and Nutrition (NIHN)	Japan
Nordic Council of Ministers (Nordic)	Nordic countries
International Zinc Nutrition Consultative Group (IZiNCG).	International

Starting in 2013, the remaining 2009 draft NRVs-R for 8 vitamins and minerals from WHO/FAO (2004) and 7 other minerals from IOM (1997, 2001, 2005) were subsequently considered, including relevant conversion factors and footnotes.

The decision-making process was considerably detailed to ensure derivation of the reviewed NRVs-R was as scientific and objective as possible. This required consideration of appropriate reference sources, the basis of the DIRVs, and application of a standardized approach.

The following sections detail each of these aspects followed by summaries of the reviews of the 15 draft NRVs-R. Subsidiary considerations for conversion factors and footnotes are also given. The completion of the work resulted in a mix of revised and new NRVs-R, a few NRVs-R with the same value as their preceding NRV, and decisions not to establish NRVs-R for certain minerals.

6.2.3 DIRV parameters

In selecting the most appropriate DIRV as the basis for an NRV-R, it was important to consider various parameters in the evidence base. CCNFSDU (2013) considered the following DIRV parameters in the RASB reference sources. These details were adapted from the Committee's 2010 request to FAO/WHO. The parameters were:

- the DIRVs (value, unit) for males and females in one or more age ranges that span 19–50 years;
- physiological endpoint used to establish the DIRV;
- the reason for the choice of endpoint;
- coefficient of variation used to derive the INL98;
- whether derived from primary evaluation; if not, whether adopted, or adapted from DIRVs from one more countries;
- reference body weights for males and females aged 19–50 years and their basis, i.e. current population data or recommendations for health as appropriate;
- percentage dietary absorption and its basis;
- year of scientific evaluation of DIRV;
- year of latest reference cited in the evaluation.

6.2.4 Stepwise procedure

A stepwise procedure was needed to ensure consistent decision-making over time. From early use of the procedure, it became clear that the EWG could not always agree on the most appropriate NRV-R. An alternative step 5b (Table 9) was introduced to allow highly similar DIRVs to constitute the basis of an NRV-R. DIRVs could be averaged if two or more similarly valued DIRVs based on the same physiological endpoint were supported by the EWG. Having this option enabled the EWG to make recommendations to CCNFSDU on a case-by-case basis when more than one DIRV was closely supported.

Table 9
Stepwise procedure was needed to ensure consistent decision-making

Step 1	Consider the potential unsuitability of DIRVs from FAO/WHO according to General Principle 3.1.1
Step 2	Identify DIRVs established by the accepted RASBs for the vitamins and minerals under consideration according to General Principle 3.1.2.
Step 3	For each vitamin and mineral, calculate adult candidate DIRVs from the accepted RASB, including from FAO/WHO where applicable, in accordance with General Principles 3.2.1.1, 3.2.1.2 and 3.2.1.3.
Step 4	Compare each candidate DIRV with General Principle 3.3 and set aside those found to be unsuitable
Step 5a OR	From consideration of the differences between suitable candidate DIRVs, recommended the most appropriate NRV-R
Step 5b	From consideration of the differences between highly similar and suitable candidates DIRVs, average the DIRVs to recommend a representative NRV-R.

6.3

Phase 3: NRVs-R from FAO/WHO and other reference sources

6.3.1 NRVs-R revised from previous NRVs

Three NRVs for vitamin C, zinc and magnesium were revised after consideration of candidate DIRVs from RASBs and FAO/WHO.

Vitamin C

Review of the NRV involved a decision on the relevant physiological endpoint for the INL50 as the selected endpoint heavily influenced the final value. All DIRVs were INL98 and considerably below the UL for young children. Table 10 gives details for the physiological endpoint and rationale to indicate the differences.

Table 10
Vitamin C – candidate DIRVs, physiological endpoint and rationale

RASB (Year)	Candidate DIRV (mg)	Physiological endpoint and reason for its choice
WHO/FAO (2004)	45	Amount required to half saturate body tissues with vitamin C in 97.5% population. Assumed this is best indicator of adequacy available.
IOM (2000)	83	Estimates of adequate body pool or tissue levels to provide antioxidant protection with little or no urinary loss. Based on 80% maximal neutrophil concentration, i.e. halfway between level at which no urinary excretion occurs and maximum level at which 25% excretion occurs.
EFSA (2013a)	103	Maintenance fasting plasma ascorbate concentrations at about 50 µmol/litre. Such concentrations at 40–50 µmol/litre correspond to near saturation of body pools (adequate status) with minimal urinary excretion.
NIHN (2013)	100	Maintenance fasting plasma ascorbate concentrations at about 50 µmol/litre. Optimal plasma antioxidant activity helping to reduce the risk of cardiovascular disease is achieved by a plasma ascorbic acid concentration of 50 µmol/litre.
Nordic Council of Ministers (2014)	75	Intake needed to achieve plasma ascorbate concentration of 32 µmol/litre with additional 25% allowance for intra-individual variance.
1993 NRV	60	

Most of the EWG preferred a physiological endpoint of near saturation of body tissues, which excluded the candidate DIRV from WHO/FAO (2004). Selected candidate DIRVs were therefore in the range 80–105 mg. The two most recent reviews of these DIRVs were from EFSA (2013a) and the National Institute of Health and Nutrition (NIHN) (2013), which had selected a maintenance fasting plasma ascorbate concentration of 50 µmol/litre as the endpoint, and their DIRVs were close to the top of the range. According to Step 5b of the stepwise procedure, these two candidate DIRVs were averaged $(100 + 103)/2 = 102$ and rounded down to 100 mg.

Conclusion

CCNFSDU (2014) agreed to establish an NRV-R of 100 mg revised up from the NRV of 60 mg.

Zinc

The 2009 draft NRV-R for zinc based on WHO/FAO (2004) consisted of three DIRVs as INL98 for diets of low, medium and high zinc bioavailability. These were subsequently expressed in percentage terms in WHO/FAO (2006). The term **bioavailability** was not adopted because the meaning of this term in the Codex Nutritional Risk Analysis Principles and Guidelines (Codex Alimentarius Commission Procedural Manual) refers to utilization in metabolism as well as intestinal absorption. The cited WHO/FAO documents discuss only **absorption** so this term was adopted in relation to the reviewed zinc (Table 11) and iron NRVs-R.

Table 11
Zinc – candidate DIRVs

RASB	INL98 or AI	Candidate DIRV (mg)
WHO/FAO (2004; 2006)	INL98	3.6 (50% absorption) 6 (30% absorption); 12 (15% absorption)
IOM (2001)	INL98	10 (41% absorption)
EFSA (2014a)	INL98	8.5–14.5 depending on dietary phytate
NIHN (2013)	INL98	11
IZiNCG (2004)	INL98	11 (30% absorption); 14 (22% absorption)
1993 NRV		15

The EWG considered multiple NRVs-R according to dietary zinc absorption and related dietary patterns. This was because the annex preamble anticipated the need for governments to take account of country or region specific factors in setting NRVs-R. This preference for multiple NRVs-R representing different percentage absorptions then limited consideration of candidate DIRVs to the International Zinc Nutrition Consultative Group (IZiNCG) and EFSA, as well as WHO/FAO (2006).

IZiNCG (2004) had updated the DIRVs from WHO/FAO (2004) and IOM (2001) by revising the factorial contribution to endogenous zinc losses from more studies of the same methodologic type. Its report included total diet studies only, in contrast to WHO/FAO (2004) and IOM (2001). Two candidate DIRVs representing dietary absorptions of 30 percent (11 mg) and 22 percent (14 mg) were available as well as dietary descriptions and young child ULs. EFSA (2014a) DIRVs were established according to four levels of dietary phytate, which would also require knowledge of dietary phytate content.

The EWG preferred the two IZiNCG (2004) DIRVs and related dietary descriptions because they were internationally applicable and more recent than WHO/FAO (2004). The two DIRVs were compared with the IZiNCG (2004) ULs for young children, noting that insufficient data existed to set a UL with confidence. The lower DIRV was higher than the 1–3 year UL but lower than the 4–8 year UL. The EWG preferred two DIRVs representing the two percentage zinc absorptions with accompanying dietary descriptions from IZiNCG (2004). On that basis, a footnote advising selection of the more appropriate percentage absorption was also agreed.

Dietary descriptions	
30% absorption	Mixed diets and lacto ovo vegetarian diets that are not based on unrefined cereal grains or high extraction rate (> 90%) flours).
22% absorption	Cereal based diets, with > 50% energy intake from cereal grains or legumes and negligible intake of animal protein.
Footnote	
Competent and/or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets.	

Conclusion

CCNFSDU (2014) agreed to establish two NRVs-R for zinc of 11 mg (30 percent absorption) and 14 mg (22 percent absorption), revised from the NRV of 15 mg. Descriptions of the two related dietary patterns accompanied the NRVs-R. A new footnote advised selecting the more appropriate NRV-R.

Magnesium

Candidate DIRVs from 4 RASBs in the range 315–365 mg were based on balance studies except for one AI based on dietary intake (Table 12). The young child UL was not relevant because it was relevant only to fortificant or supplement forms of magnesium.

Table 12
Magnesium – candidate DIRVs

RASB	INL98 or AI	Candidate DIRV (mg)
WHO/FAO (2004)	INL98	240 (a provisional estimate)
IOM (1997)	INL98	365
EFSA (2015a)	AI (diet)	325
NIHN (2013)	INL98	320
Nordic Council of Ministers (2014)	Recommended intake No (INL50)	315
1993 NRV		300

In keeping with the General Principles, the EWG selected all INL98 values from three RASBs and WHO/FAO (2004). According to Step 5b of the stepwise procedure, the four candidate DIRVs from IOM (1997), NIHN (2013), Nordic Council of Ministers (2014) and WHO/FAO (2004) were averaged ($[365 + 320 + 315 + 240]/4$) to 310 mg.

Conclusion

CCNFSDU (2015) agreed to establish an NRV-R for magnesium of 310 mg revised up from the NRV of 300 mg.

6.3.2 NRVs-R with same value as NRV and additional information

Reviews of NRVs for vitamin D and iron maintained the same value but more information was included after consideration of candidate DIRVs from RASBs and WHO/FAO (2004).

Vitamin D

Consideration of the DIRVs for vitamin D included DIRVs both as INL98 and AI based on the dietary intake to achieve serum 25 hydroxy vitamin D levels, mostly 50 nmol/litre at minimal or other sunlight exposures (Table 13). However, the EWG recognized that dietary vitamin D may not be needed where sufficient sunlight exposure occurs, as in some countries. Because recently established DIRVs were higher than the 2009 draft NRV-R of 5 µg from WHO/FAO (2004), the EWG supported a higher NRV-R. However, consensus could not be reached on whether 10 µg or 15 µg was more appropriate. Both DIRVs were considerably below the young child ULs.

Table 13
Vitamin D – candidate DIRVs

RASB	INL98 or AI	Candidate DIRV (µg)
WHO/FAO (2004)	RNI (AI)	5
IOM (2011)	INL98	15
NHMRC/MOH (2006)	AI	5
NIHN (2013)	AI	5.5
Nordic Council of Ministers (2014)	INL98	10
1993 NRV		5

CCNFSDU (2015) decided to wait for the EFSA (2016a) DIRV due the following year and revised the existing footnote “Nutrient Reference Values for Vitamin D, Niacin and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.6.1 of the Codex Guidelines on Nutrition Labelling.” The revised footnote deleted reference to iodine and niacin and modified the vitamin D text to the effect that authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors.

CCNFSDU (2016) recognized the variation in requirement based on different levels of sunlight exposure around the world and noted the General Principles provided for ranges to be established. The EFSA DIRV of 15 µg (AI) was equivalent to the candidate IOM DIRV

(2011) (INL98) under conditions of minimal sunlight exposure. A first sentence was added to the previously revised footnote to explain the basis of the higher level. Therefore, the NRV-R for vitamin D was set in a range of 5–15 µg based on WHO/FAO (2004) at the lower bound (same as the previous NRV), and on DIRVs of the same value from IOM (2011) and EFSA at the higher bound.

Footnote

The value of 15 µg is based on minimal sunlight exposure throughout the year. Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors.

Conclusion

CCNFSDU (2016) agreed to establish an NRV-R for vitamin D of 5–15 µg to extend the previous NRV of 5 µg. A new footnote in place of the original footnote was also agreed by CCNFSDU (2015), and elaborated by CCNFSDU (2016) to guide selection of an appropriate NRV-R, noting the basis for the upper bound of the NRV-R range.

Iron

Based on the approach for zinc, the EWG considered that multiple NRVs-R according to dietary iron absorption with descriptions of associated dietary patterns would be useful for Codex members to determine an appropriate NRV-R. The EWG preferred internationally derived multiple NRVs-R according to percentage absorption, which then limited consideration of candidate DIRVs to WHO/FAO (2004). All other candidate DIRVs were based on single iron absorptions from national diets (Table 14).

Table 14
Iron – candidate DIRVs

RASB	Candidate DIRV (mg) (all INL98 except EFSA: INL95)
IOM (2001)	13 (18% absorption)
EFSA (2015f) draft	13.5 (17% absorption)
NIHN (2013)	9 (15% absorption)
WHO/FAO (2004)	14 (15% absorption) 18 (12% absorption) 22 (10% absorption) 43 (5% absorption)
Nordic Council of Ministers (2014)	12 (15% absorption)
1993 NRV	14

Listing all 4 WHO/FAO (2004) DIRVs was considered unnecessary particularly as 12–15 percent absorption was advised as appropriate for western-type diets depending on meat intake, and 5–10 percent was appropriate for other diets. For comparison, the percentage absorption ranged from 10 percent to 18 percent for DIRVs from RASBs. On this basis, the

EWG selected 15 percent and 10 percent to represent high and intermediate dietary absorption in many countries around the world. The two candidate DIRVs of 14 mg and 22 mg were considerably below the UL for young children.

The dietary descriptions were available from FAO/WHO (2004) and (2006). The EWG modified them in terms of food rather than nutrients to be more consistent with zinc dietary descriptions.

Dietary descriptions	
15% absorption	Diversified diets, rich in meat, fish, poultry and/or rich in fruit and vegetables
10% absorption	Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables

Conclusion

CCNFSDU (2015) agreed to establish two NRVs-R for iron of 14 mg (15 percent absorption) and 22 mg (10 percent absorption), revised from a single NRV of 14 mg. Descriptions of the two related dietary patterns accompanied the NRVs-R. The new footnote that applied to zinc NRV-R was also applied to the iron NRV-R.

6.3.3 NRVs-R with same value as NRV

Review of the NRVs for vitamin A and protein resulted in the same value for the NRVs-R after consideration of candidate DIRVs from RASBs and FAO/WHO.

Vitamin A

Three candidate DIRVs, all INL98, from RASBs and also from WHO/FAO (2004) were considered, all of which were based on the same factorial approach and physiological endpoints of adequate retinol stores in liver or adequate total body pool (Table 15). The EWG preferred DIRVs in the range 700–800 µg, which exceeded the 2009 draft NRV-R of 550 µg.

Table 15
Vitamin A – candidate DIRVs

RASB	Candidate DIRV (µg)
WHO/FAO (2004)	550
IOM (2001)	800
EFSA (2015b)	700
NIHN (2013)	765
1993 NRV	800

The preferred range was compared with the ULs for the two young child age groups and found to be equivalent to or exceed the ULs for 1–3 years, but below the ULs for 4–6/8 years. Given the conservative nature of the comparison with the ULs, CCNFSDU (2015) agreed to establish the NRV-R at 800 µg based on IOM (2001), noting this was the value of the NRV in the Guidelines.

Conversion factors

The EWG reviewed the footnote in the Guidelines on Nutrition Labelling relating to the conversion factor: “for the declaration of β-carotene, the following conversion factor should be used: 1 µg retinol = 6 µg β-carotene”.

The conversion factors from several RASBs and FAO/WHO were examined by the EWG, which noted no international consistency in the name applied or conversion factors for vitamin A dietary equivalents.

Two sets of names used for vitamin A dietary equivalents refer to different ratios of retinol: β-carotene: provitamin carotenoids (α-carotene and β-cryptoxanthin). They are:

- retinol activity equivalents (RAE), ratio 1:12:24
- retinol equivalents (RE), ratio 1:6:12.

WHO/FAO (2004) referred to RE and its ratio, whereas WHO/FAO (2006) and subsequent publications adopted the first mentioned ratio while retaining the name RE. The Committee could not achieve consensus so included both sets of names and dietary equivalents as alternatives in the new table of conversion factors (see Appendix 3).

Conclusion

CCNFSDU (2015) agreed to establish an NRV-R for vitamin A of 800 µg, which is the same value as the previous NRV, and to add both sets of conversion factors to the table as alternatives.

Protein

The DIRV and supplementary information for protein were considered by the EWG in two parts: candidate DIRVs (g) per kilogram body weight, and application of various RASB body weights to produce DIRVs expressed in grams. There was no UL for protein for young children.

Candidate DIRVs were selected from WHO/FAO/UNU (2007) and 4 RASBs, all within the range 0.8–0.9 g/kg body weight as shown in Table 16.

Table 16
Protein – candidate DIRVs

RASB	Candidate DIRV / (kg b wt/day)
WHO/FAO/UNU (2007)	0.83
EFSA (2012)	0.83
IOM (2002–2005)	0.8
NHMRC/MOH (2006)	0.8 (average M, F)
NIHN (2013)	0.9

The WHO/FAO (2007) DIRV of 0.83 kg/b wt was considered a primary source, and so the percentage difference from the mean of the DIRVs from RASBs was calculated. This value fell within ± 10 percent of the mean of DIRVs from RASBs (0.84 ± 0.08 g/kg/b wt) and was supported by the EWG.

The second part related to selection of reference body weights for adult males and females. WHO/FAO (2007) did not provide a reference body weight for adult males and females but instead recommended protein DIRVs in 10 kg increments of adult body weight. Therefore, reference body weights from an earlier FAO/WHO expert consultation (FAO/WHO,1988b) and the above RASBs were considered (Table 17).

Table 17
Protein – reference body weights

RASB (age [years])	Reference adult body weight (kg)		Basis
	Male	Female	
FAO/WHO (1988b) (18+)	65	55	Based on (USA) National Center for Health Statistics (NCHS) / Centers for Disease Control and Prevention (CDC) 1977 growth reference data as cited by IZiNCG
EFSA (2013b) (18–79)	68.1	58.5	Median body weight based on measured body heights and assuming body mass index (BMI) of 22 kg/m ²
IOM (2002–2005) (19+) [from 2002]	70	57	2002 onwards: CDC/NCHS growth charts using median height and median BMI for 19 year olds (22.5 [M]; 21.5 [F])
NHMRC/MOH (2006) (19+)	76	61	Average body weights for 19–30 year olds from Australia or New Zealand national health surveys: 1995, 1997, 2002
NIHN (2013) (18-29)	63.5	50	Median body weights for 18–29 / 30–49 year old men and women from 2005 and 2006 National Health and Nutrition Surveys in Japan.

Body weights for males and females from these RASBs ranged respectively from 63–76 kg to 50–61 kg. These were based either on surveyed body weights of young adults, or application of body mass index (BMI) 22 kg/m² to median or surveyed body heights.

To test the impact of different body weights on an NRV-R for protein, the mean adult male and female reference body weights from FAO/WHO (1988b) and the 4 RASBs were applied



to 0.83 g/kg with the result ranging from 47 g to 56 g. Applying the FAO/WHO (1988b) mean reference adult body weight of 60 kg resulted in a DIRV of 50 g. This value fell within ± 10 percent of the mean of the DIRVs (52 g) calculated from the respective mean adult body weights of the 4 RASBs (mean 63 kg). The previous NRV of 50 g was derived from $0.75 \text{ g/kg} \times 70 \text{ kg man}$ (52.5 g rounded down to 50 g).

Conclusion

CCNFSDU (2013) agreed to establish an NRV-R for protein of 50 g, which is the same value as the previous NRV.

6.3.4 New NRVs-R

New NRVs-R were established after consideration of candidate DIRVs from RASBs and FAO/WHO for vitamin E, selenium, copper, phosphorus, molybdenum and manganese.

Vitamin E

The DIRVs for vitamin E given as INL98 were officially advised as set too high or were older theoretically derived values. All other DIRVs including from WHO/FAO (2004) were AIs based on dietary intakes in the range 7–12 mg (Table 18). All candidate DIRVs were below the UL for young children.

Table 18
Vitamin E – candidate DIRVs

RASB	INL98 or AI	Candidate DIRV (mg)
WHO/FAO (2004)	RNI (AI)	8.8 (rounded to) 9
IOM (2000)	INL98	15
EFSA (2015c)	AI	12
NHMRC/MOH (2006)	AI	8.5
NIHN (2013)	AI	6.8
Nordic Council of Ministers (2014)	INL98	9
Average of EFSA, NHMRC/MOH, NIHN, WHO/FAO	AI	$(12 + 8.5 + 6.8 + 8.8)/4 = 9$

Given the uncertainty of the information, the EWG considered averages of different combinations of RASBs and preferred an average of 4 AIs from EFSA, NHMRC/MOH, NIHN, and WHO/FAO $(12 + 8.5 + 6.8 + 8.8)/4 = 9$, which was the same value as the older INL98 from the Nordic Council of Ministers.

Conversion factors

The conversion factors from several RASBs and WHO/FAO were examined by the EWG, which noted no international consistency on whether conversion factors for vitamin E dietary equivalents were needed.

Four RASBs – IOM, EFSA, NIHN, and Nordic Council of Ministers and WHO/FAO (2006) – referred only to RRR- α -tocopherol as the dietary isomer with vitamin E activity; whereas NMHRC/MOH and WHO/FAO (2004) referred to alpha-tocopherol equivalents with conversion factors for 3 tocopherols and 1 or 2 tocotrienols.

The view in support of the single isomer indicated that only naturally occurring RRR- α -tocopherol is maintained in the plasma through preferential binding in the liver to a specific transfer protein. The other view indicated that it was premature to discount vitamin E activity for γ -tocopherol, the other major tocopherol in food, as it was present in plasma despite the absence of a specific protein. The other tocopherols and tocotrienols were also supported by some delegations.

The EWG considered the practical impact of basing dietary vitamin E intakes on RRR- α -tocopherol alone or alpha-tocopherol equivalents. The EWG noted EFSA (2015c) had reviewed national European intakes calculated according to both approaches, and had concluded that results were close. EFSA also noted the uncertain extent of comprehensive alpha-tocopherol equivalents data used to derive the dietary intakes.

After much discussion, CCNFSDU (2016) agreed that 1 mg α -tocopherol was equivalent to 1 mg RRR- α -tocopherol. This position was included in the table of dietary equivalents to provide clarity, while noting the footnote below the table indicated the purpose of the table was to provide supporting information (see Appendix 3).

Conclusion

CCNFSDU (2015) agreed to establish a new NRV-R for vitamin E of 9 mg, and CCNFSDU (2016) agreed to clarify the units of dietary equivalents for vitamin E in the table.

Selenium

For selenium, the EWG preferred endpoints based on maximal plasma glutathione peroxidase activity or the more recent maximum saturation of selenoprotein P1 as an indicator of saturation of the functional body pool. Candidate DIRVs were therefore in the range 55–65 μg (Table 19). One INL98 slightly exceeded one of the two ULs for 1–3 year olds, but not those for 4–6/8 year olds. In accordance with Step 5b of the stepwise procedure, the three respective candidate DIRVs were averaged $(55 + 65 + 55)/3 = 58 \mu\text{g}$.

Table 19
Selenium – candidate DIRVs

RASB	Candidate DIRV (μg) (INL98 except EFSA)
WHO/FAO (2004)	30
IOM (2000)	55
NHRMC/MOH (2006)	65
NIHN (2013)	28
Nordic Council of Ministers (2014)	55
Average of IOM, NHRMC/MOH, Nordic Council of Ministers	$[55 + 55 + 65] = 58$
1993 NRV	Value to be established
EFSA (2014b) draft	AI 70

However, the final EFSA scientific opinion (2014b) became available prior to the CCNFSDU session, which noted the uncertainties in the available data and set an AI of 70 µg using the selenoprotein P1 saturation endpoint. Including this value into the average raised the value slightly $(55 + 65 + 55 + 70)/4 = 61$ µg, so the Committee agreed on 60 µg as a round number.

Conclusion

CCNFSDU (2014) agreed to establish a new NRV-R for selenium of 60 µg, which replaced the indicative text, *value to be established*.

Phosphorus

Consideration of candidate DIRVs for phosphorus included three INL98 based on two different endpoints, and two AI based on limited evidence or dietary intake. The draft EFSA AI (limited evidence) was available for consideration. The EWG selected values in the range 700–800 mg based on DIRVs from IOM, draft EFSA or an average of all three INL98 (Table 20). The final EFSA (2015d) AI was revised down to 550 mg. However, the EWG continued to prefer values in the original range. While noting the reduction in the final EFSA DIRV, the Committee agreed on the DIRV of 700 mg from IOM (1997) at the lower end of the original range. It also noted that this value was lower than the NRV-R established for calcium of 1 000 mg.

Table 20
Phosphorus – candidate DIRVs

RASB	INL98 or AI	Candidate DIRV (mg)
IOM (1997)	INL98	700
EFSA (2015d) draft	AI	700
NHMRC/MOH (2006)	INL98	1 000
NIHN (2013)	AI	950
Nordic Council of Ministers (2014)	INL98	600
Average of IOM, NHMRC/MOH, Nordic Council of Ministers of Ministers	INL98	$(700 + 1\ 000 + 600)/3 = 767$ rounded to 800

Conclusion

CCNFSDU (2015) agreed to establish a new NRV-R for phosphorus of 700 mg.

Copper

For copper, the EWG preferred INL98 based on a combination of indicators in controlled depletion/repletion studies, over higher AIs based on dietary intakes. Candidate DIRVs were therefore in the range 850–900 µg (Table 21). In keeping with the original number of significant figures for male and female DIRVs (i.e. rounded to the nearest 100 µg), the INL98 from IOM (2001) was preferred.

Table 21
Copper – candidate DIRVs

RASB	INL98 or AI	Candidate DIRV (µg or mg)
IOM (2001)	INL98	900 µg
EFSA (2015e) draft	AI	1.5 mg
NHMRC/MOH (2006)	AI	1.5 mg
NIHN (2013)	INL98	800 µg
Average of IOM, NIHN.	INL98	$(900 + 800)/2 = 850$ rounded to 900
1993 NRV		Value to be established

Conclusion

CCNFSDU (2015) agreed to establish a new NRV-R for copper of 900 µg, which replaced the indicative text, *value to be established*.

Molybdenum

For molybdenum, three RASBs established candidate DIRVs based on INL98 (or AI) derived from population dietary intakes (Table 22). The general principles provided for case-by-case situations where there was a mix of INL98 and AI and the INL98 was older than a more recent AI. The Committee noted the two INL98 were based on the same single balance study, but it also pragmatically noted that the average of all three candidate DIRVs was the same as the mid value from IOM (2001) DIRV. This DIRV was selected as the basis for a new NRV-R.

Table 22
Molybdenum – candidate DIRVs

RASB	INL98 or AI	Candidate DIRV (µg)
IOM (2001)	INL98	45
EFSA (2013c)	AI	65
NIHN (2013)	INL98	26

Conclusion

CCNFSDU (2014) agreed to establish a new NRV-R for molybdenum of 45 µg.

Manganese

For manganese, four RASBs considered there was insufficient evidence to establish DIRVs as INL98 but established AIs based on population dietary intake. As such, these AIs were considered to be primarily evaluated and acceptable as candidate DIRVs (Table 23). The AIs from IOM, EFSA, NHMRC/MOH and NIHN ranged from 2.1 mg to 5.3 mg.

Table 23
Manganese – candidate DIRVs

RASB	Candidate DIRV (all AI)
IOM (2001)	2.1 mg
EFSA (2013d)	3.0 mg
NHMRC/MOH (2006)	5.3 mg
NIHN (2013)	3.75 mg
Average of IOM, EFSA, NHMRC/MOH and NIHN and round down	= 3.5 rounded down to 3 mg

Given the paucity of scientific data, some EWG members queried whether an NRV-R should be established at all for this mineral. However, the EWG considered all candidate DIRVs should be averaged given the regional representation, i.e. $(2.1 + 3.0 + 5.3 + 3.75)/4 = 3.5$. Because this value exceeded the UL for both age groups of young children, it was rounded down to 3 mg.

Conclusion

CCNFSDU (2014) agreed to establish a new NRV-R for manganese of 3 mg.

6.3.5 NRVs-R not established

Review of available DIRVs for chromium, fluoride and chloride resulted in no NRVs-R established for these minerals.

Chromium

Although two DIRVs were available from RASBs, they were based on either very limited data or a theoretical dietary intake (Table 24). Two other RASBs had not set DIRVs. The EWG supported an NRV-R for chromium; however, CCNFSDU (2015) decided there were insufficient data to establish an NRV-R for chromium.

Table 24
Chromium – candidate DIRVs

RASB	INL98 or AI or ND	Candidate DIRV (µg)
IOM (2001)	AI	30
EFSA (2014c) or Nordic Council of Ministers (2014)	ND	Not determined due to insufficient data
NIHN (2013)	INL98	35

Fluoride

DIRVs (both AIs) were available based on the contribution of fluoride to prevention of dental caries (Table 25). The EWG considered this endpoint did not relate to a nutritional requirement and, noting some concern about fluorosis, indicated that there was no nutritional basis on which to establish an NRV-R. CCNFSDU (2014) agreed not to establish an NRV-R for fluoride.

Table 25
Fluoride – candidate DIRVs

RASB	Candidate DIRV (mg) (all AI)
IOM (1997)	3.5
EFSA (2013e)	3.2



Chloride

One DIRV was available, based on an equimolar amount to the national sodium dietary reference intake (Table 26). The EWG applied the same rationale to the higher sodium NRV-NCD. However, it noted that the resultant sum of draft chloride NRV-R and sodium NRV-NCD slightly exceeded the international recommendation of no more than 5 g salt per day. The EWG preferred establishing an NRV for chloride but differed with respect to an NRV-R or NRV-NCD (outside scope of this project), or national dietary intake value or scaled up value. CCFNSDU (2015) noted the limited basis for the various options and decided not to establish an NRV-R for chloride.

Table 26
Chloride – candidate DIRVs

RASB	AI	Candidate DIRV (mg)	Basis
IOM (2002–2005)	AI	2300 (65 mmol)	Equimolar with IOM sodium DIRV of 1 500 mg
Equimolar NRV-R	N/A	3089 (87 mmol)	Equimolar with Codex sodium NRV-NCD of 2 000 mg

6.4

Summary of NRVs-R

CCNFSDU (2013–2016) agreed 13 NRVs-R comprising 3 revised, 2 same with extensions, 2 unchanged, and 6 new NRVs-R. These NRVs-R were based on a single DIRV or an average of two or more DIRVs drawn from WHO/FAO (2004) and six RASB reference sources. These NRVs-R were additional to the 11 NRVs-R from WHO/FAO (2004) agreed at CCFNSDU (2012).

The previous NRVs and present NRVs-R in Table 27 were comparable, except for vitamin C which increased considerably. Additional information for vitamin D, iron and zinc allowed for guided national discretion; new NRVs-R provided values for additional minerals including for selenium and copper, which had been intended since 1993.

Table 27
Previous NRVs and reviewed NRVs-R

Vitamin or mineral	Previous NRVs (1993)	Reviewed NRVs-R (2013–16)
Revised		
Vitamin C (mg)	60	100
Zinc (extended) (mg)	15	11 (% dietary absorption; dietary description) 14 (% dietary absorption; dietary description) (new footnote)
Magnesium (mg)	300	310
Same with extensions		
Vitamin D (µg)	5 (footnote)	5–15 (revised footnote)
Iron (extended) (mg)	14	14 (% dietary absorption; dietary description) 22 (% dietary absorption; dietary description) (new footnote)
Same		
Vitamin A (µg)	800 (RE footnote)	800 (no footnote, new table for conversion factors RAE or RE)
Protein (mg)	50	50
New		
Vitamin E (mg)		9 (new table for conversion factor)
Selenium (µg)	value to be established	60
Phosphorus (mg)		700
Copper ((µg)	value to be established	900
Molybdenum (µg)		45
Manganese (mg)		3
NRV-R not established		
Chromium		
Fluoride		
Chloride		



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Impact of NRV-R updates on stakeholders

7.1 Food manufacturers	60
7.2 Consumers	60
7.3 Trade	61

International, regional or national reference nutrient intake values may be officially published in complete sets, or updated progressively in smaller groups or individually. When NRVs-R are derived from a subset of reference nutrient intake values, food regulators need to consider carefully how to best update NRVs-R to reflect the latest recommendations.

While updating NRVs-R in food regulation may be a straightforward process, such changes can have a disproportionately large impact on food manufacturers and consumers. Because of this, there may be decades between revisions of reference nutrient intake values and consequential updates to NRVs. NRVs are generally not updated until after completion of revision of all reference nutrient intake values. This is to enable NRVs-R to be updated at one time in order to limit manufacturing costs and to maximize the salience of any consumer education.

7.1

Food manufacturers

Any change to labelling regulations increases manufacturing costs. However, these can be partially mitigated through appropriate transition arrangements. If % NRVs-R are declared on a food label, changing the value of NRVs-R in food regulation without concomitant food reformulation will automatically require a change in the declared % NRV-R.

A manufacturer's eligibility to make nutrition claims (and health claims) may also change if the conditions for such claims are based on a minimum % NRV-R.

Depending on the extent of change, a decrease in NRV-R may provide a new opportunity for a new or upgraded nutrient content claim, e.g. from *source* to *good source*. Conversely, an increased NRV-R may downgrade a nutrient content claim from *good source* to *source*, or become ineligible altogether. Faced with potential ineligibility, a manufacturer wishing to maintain the claim may reformulate the food by increasing nutrient content through direct addition if permissible, or modifying the recipe or source of ingredients to meet the new claim conditions.

7.2

Consumers

Nutrition claims inform consumers about the nutrient content of a food. The % NRVs-R enable consumers to assess the contribution of a portion of food to their daily nutrient needs and so help them make choices that contribute to an overall healthful dietary intake. This is particularly the case when consumer education programmes accompany nutrition labelling to explain how they should be used.

When % NRV-R or related label claims change in the absence of changes to food formulation, consumers may become confused or even suspicious that manufacturers are concealing changes to food composition. This is because the actual NRVs are in the background and, if not publicly available or widely publicized, consumers are likely to be unaware when changes to NRVs-R are made.

Consider the effects of increasing the calcium NRV-R on milk labels that declare calcium content in a 200 ml serving.

Calcium /200 ml	NRV	% NRV
200 mg	800 mg	25%
	1 000 mg	20%

Without additional information, consumers may consider the milk to have “lost” some of its calcium content. Therefore, it is important for regulators together with food manufacturers to inform consumers how to best use % NRV-R information and about the impact of updates to this information when changes to % NRV-R are made on food labels.

7.3

Trade

Codex standards, guidelines and other recommendations are developed to provide consumer protection and facilitate fair trade practices. The two Codex nutrition labelling guidelines were developed through consensus and represent global opinion on appropriate nutrition labelling. Countries are encouraged to adopt nutrition labelling consistent with these guidelines. Because nutrition labelling must be meaningful to local populations, national regulators can make full use of the guidelines’ inherent flexibility, principles and criteria to establish appropriate regulation. Multiple NRVs-R for iron and zinc, and the vitamin D NRV-R given as a range, take account of the differences in local diets or local environments.

Although use of NRVs-R for nutrient declaration in the Guidelines on Nutrition Labelling is optional, NRVs are used as the basis of nutrition claims in the Guidelines for Use of Nutrition and Health Claims. Therefore, they serve the information needs of food manufacturers and consumers and are established in the interests of international standardization and harmonization.

Different sets of NRVs-R are given in food regulations around the world. Nevertheless, countries take account of the Codex guidelines when updating their regulations. Countries that adopt FAO/WHO reference nutrient intake values may also adopt the Codex NRVs-R in nutrition labelling, whereas countries that have their own reference nutrient intake values may take the Codex NRVs into account.

Nutrition Facts

Sugars, brown

Serving Size 100g/3.5oz

Amount

% Daily Value

Calories 377

Calories from Fat 0

Total Fat 0 g

Saturated Fat 0 g

0%

Trans Fat 0 g

0%

Cholesterol 0 mg

Sodium 35 mg

0%

Carbohydrate 98 g

2%

Fiber 0 g

33%

Sugars 97 g

0%

0 g

Codex Information Document

In recognition of the large amount of complex and technical work undertaken to review the NRVs, an information document providing the derivation of each NRV-R was compiled. It details the NRV-R, the type of DIRV that served as the basis of the value, the RASB source documents of the selected DIRVs, and the relevant CCNFSDU report of the final decision.

CCNFSDU Information document

1

INFORMATION DOCUMENT
DERIVATION OF NUTRIENT REFERENCE VALUES- REQUIREMENTS (NRVs-R) FOR
LABELLING PURPOSES IN THE *GUIDELINES ON NUTRITION LABELLING (CXG 2-1985)*

Nutrient	NRV-R	INL ₉₈ , AI, or both	RASB source documents for derivation of NRVs-R	CCNFSDU Report
Vitamins				
Vitamin A	800 µg (RAE or RE)	INL ₉₈	IOM (2001)	REP 16/NFSDU, 2015
Vitamin D*	5 – 15 µg	INL ₉₈ and A ₁	WHO/FAO (2004) IOM (2011), EFSA (2016)	REP 17/NFSDU, 2016
Vitamin C	100 mg	INL ₉₈	Average EFSA (2013), NIH (2013)	REP 15/NFSDU, 2014
Vitamin E	9 mg	AI	Nordic Council (2013), and average of EFSA (2015), NHRMC/MOH (2006) , NIH (2013), WHO/FAO (2004)	REP 16/NFSDU, 2015 REP 17/NFSDU, 2016
Vitamin K	60 µg	INL ₉₈	WHO/FAO (2004)	REP 13/NFSDU, 2012
Thiamin	1.2 mg	INL ₉₈	WHO/FAO (2004)	REP 13/NFSDU, 2012
Riboflavin	1.2 mg	INL ₉₈	WHO/FAO (2004)	REP 13/NFSDU, 2012
Niacin	15 mg NE	INL ₉₈	WHO/FAO (2004)	REP 13/NFSDU, 2012

This information document is previewed above and is available on the Codex website at:
www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_CCNFSDU_e.pdf



Reflections and the future of NRVs-R

The completion of the review of NRVs-R in 2016 brought to a conclusion CCNFSDU's review that developed general principles to support decision-making, and set new or revised NRVs-R for 26 vitamins, minerals and protein. This review adopted a forward-looking approach and invested time in developing a framework for the current and future revisions of NRVs-R. This was a more complex and technical process for Committee delegations to undertake than their adoption in 1993 of the recommendations of a 1988 FAO/WHO expert consultation.

Before completion in 2016, several countries and one region had updated their own reference nutrient intake values using primary evidence. This global landscape provided experience and material to guide development of the general principles, as well as a rich field of candidate NRVs-R for consideration.

In one sense, the work is not yet finished. The 2007 project plan anticipated that a suite of NRVs-R would be developed for population groups other than the general population. CCNFSDU is currently progressing work to consider NRVs-R for older infants and young children. Although some key differences in setting NRVs-R for this age group have become apparent, the basis for the consideration and selection of NRVs-R for the general population will greatly assist and make for a more efficient process in establishing NRVs-R for older infants and young children.

NRVs-R from this review for the general population are expected to stand the test of time for the next 10–20 years. This time frame reflects the review cycle of national reference nutrient intake values that may continue to be a basis of NRVs-R. The challenge for CCNFSDU will be to determine the priority for any future review, noting that, with the new framework, the consideration need focus only on revision of the NRVs-R themselves. Moreover, depending on the frequency of updates to national/regional reference nutrient intake values, it may not be necessary to review all NRVs-R.

Information for consumers about the nutritional contribution of foods to a healthy diet is expected to fulfil an information need into the future, and NRVs-R will continue to play a role in providing an interpretive element for nutrition labelling and claims about foods.

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Appendixes

Appendixes 1–3 show the original and subsequent versions of reference values for nutrients, conversion factors and footnotes in the Codex Guidelines on Nutrition Labelling. Appendix 4 shows the current (2018) version of the Annex to the Codex Guidelines on Nutrition Labelling.

Appendix 1

Guidelines on Nutrition Labelling
(CXG 2-1985)
(CCFL, 1985; ALINORM 85/22A, Appendix III)

Appendix 2

Guidelines on Nutrition Labelling
(CXG 2-1985, Rev.1-1993)
(CCFL, 1993; ALINORM 93/22, Appendix II)

Appendix 3

Guidelines on Nutrition Labelling
(CXG 2-1985, Revised in 1993 and 2011. Amended in 2003, 2006, 2009, 2010, 2012, 2013, 2015, 2016 and 2017)

Appendix 4

Guidelines on Nutrition Labelling
ANNEX adopted in 2011. Revised in 2013, 2015, 2016 and 2017.
General principles for establishing nutrient reference values for the general population.

Appendix 1 Guidelines on Nutrition Labelling

(CXG 2-1985)

(CCFL, 1985; ALINORM 85/22A, Appendix III)

3.3.4 Numerical information on nutrients should be expressed in metric units and/ or as a percentage of the Reference RDA per 100 g or per 100 ml; and /or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions in the package is stated. In addition, the information on energy value and protein may also be expressed as percentages of Reference RDA. When Reference RDAs are used they should be based as far as possible on nutrient intakes recommended by FAO/WHO. Until these have been reviewed, the following values should be used as Reference RDA for labelling purposes in the interests of international standardization and harmonization:

Energy MJ (kcal)	9.5 (2300)
Protein g	50
Vitamin A µg	1000
Vitamin D ug	5
Vitamin E mg	10
Vitamin C mg	60
Thiamin mg	1.4
Riboflavin mg	1.6
Niacin mg	18
Vitamin B6 mg	2
Folacin ug	400
Vitamin B12 ug	3
Calcium mg	800
Phosphorus mg	800
Iron mg	14
Magnesium mg	300
Zinc mg	15
Iodine ug	150

3.3.5 In countries where serving sizes are normally used, the information required by sections 3.3.2, 3.3.3, and 3.3.4 may be given only per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

Appendix 2 Guidelines on Nutrition Labelling

(CXG 2-1985, Rev.1-1993)

(CCFL, 1993; ALINORM 93/22, Appendix II)

3.3.4 Numerical information on vitamins and minerals should be expressed in metric units and/or as a percentage of the Nutrient Reference Value per 100 g or per 100 ml or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated. In addition, information on protein may also be expressed as percentages of the Nutrient Reference Value.

The following Nutrient Reference Values should be used for labelling purposes in the interests of international standardization and harmonization*:

Protein	(g)	50
Vitamin A	(µg)	800**
Vitamin D	(µg)	5***
Vitamin C	(mg)	60
Thiamine	(mg)	1.4
Riboflavin	(mg)	1.6
Niacin	(mg)	18***
Vitamin B6	(mg)	2
Folic acid	(µg)	200
Vitamin B12	(µg)	1
Calcium	(mg)	800
Magnesium	(mg)	300
Iron	(mg)	14
Zinc	(mg)	15
Iodine	(µg)	150***
Copper	Value to be established	
Selenium	Value to be established	

* In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list nutrient reference values should be kept under review.

** For the declaration of β-carotene (provitamin A) the following conversion factor should be used: 1 µg retinol = 6 µg β-carotene

*** Nutrient Reference Values for Vitamin D, Niacin and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.4.1 of the Codex Guidelines on Nutrition Labelling

Appendix 3 Guidelines on Nutrition Labelling

(CXG 2-1985, Revised in 1993 and 2011.

**Amended in 2003, 2006, 2009, 2010, 2012, 2013, 2015,
2016 and 2017)**

3.4.4 Numerical information on vitamins and minerals should be expressed in metric units and/or as a percentage of the NRV per 100 g or per 100 ml or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated. In addition, information on protein and additional nutrients may also be expressed as percentages of the NRV where an NRV has been established. The following NRVs are for the general population identified as individuals older than 36 months. They should be used for labelling purposes to help consumers make choices that contribute to an overall healthful dietary intake. They comprise two types of NRVs: Nutrient Reference Values-Requirements (NRVs-R) and Nutrient Reference Values – Non-communicable Disease (NRVs-NCD).

3.4.4.1 NRVs-R

Vitamins	
Vitamin A (µg RAE or RE)	800
Vitamin D (µg)	5 – 15*
Vitamin C (mg)	100
Vitamin K (µg)	60
Vitamin E (mg)	9
Thiamin (mg)	1.2
Riboflavin (mg)	1.2
Niacin (mg NE)	15
Vitamin B6 (mg)	1.3
Folate (µg DFE)	400
Vitamin B12 (µg)	2.4
Pantothenate (mg)	5
Biotin (µg)	30
Minerals	
Calcium (mg)	1 000
Magnesium (mg)	310

Iron (mg)**	14 (15% dietary absorption; Diversified diets, rich in meat fish, poultry, and/or rich in fruit and vegetables)
	22 (10% dietary absorption; Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables)
Zinc (mg)**	11 (30% dietary absorption; Mixed diets, and lacto-ovo vegetarian diets that are not based on unrefined cereal grains or high extraction rate (>90%) flours)
	14 (22% dietary absorption; Cereal-based diets, with >50% energy intake from cereal grains or legumes and negligible intake of animal protein)
Iodine (µg)	150
Copper (µg)	900
Selenium (µg)	60
Manganese (mg)	3
Molybdenum (µg)	45
Phosphorus (mg)	700
Other	
Protein (g)	50

* The value of 15 µg is based on minimal sunlight exposure throughout the year. Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors.

** Competent national and/or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets

Conversion factors for vitamin equivalents

Vitamin	Dietary Equivalents	
Niacin	1 mg niacin equivalents (NE) =	1 mg niacin 60 mg tryptophan
Folate	1 µg dietary folate equivalents (DFE) =	1 µg food folate 0.6 µg folic acid added to food or as supplement consumed with food 0.5 µg folic acid added to food or as supplement taken on an empty stomach
Vitamin A	1 µg retinol activity equivalents (RAE) =	1 µg retinol 12 µg β-carotene 24 µg other pro-vitamin A carotenoids
	OR 1 µg retinol equivalents (RE) =	1 µg retinol 6 µg β-carotene 12 µg other pro-vitamin A carotenoids
Vitamin E	1 mg α-tocopherol	1 mg RRR-α-tocopherol (d-α-tocopherol)

The conversion factors for vitamin equivalents in the Table provide supporting information to enable competent national and/or regional authorities to determine appropriate application of NRVs-R.

Appendix 4 Guidelines on Nutrition Labelling

ANNEX adopted in 2011.

Revised in 2013, 2015, 2016 and 2017.

General principles for establishing nutrient reference values for the general population

1. PREAMBLE

These Principles apply to the establishment of Codex nutrient reference values (NRVs) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products.

Governments are encouraged to use the NRVs, or alternatively, consider the suitability of the general principles below including the level of evidence required, and additional factors specific to a country or region in establishing their own reference values for labelling purposes. For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. In addition, governments may establish reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

2. DEFINITIONS

Daily Intake Reference Values as used in these Principles refer to reference nutrient intake values provided by FAO/WHO or recognized authoritative scientific bodies that may be considered in establishing an NRV based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g. as a single value or a range), and are applicable to the general population or to a segment of the population (e.g. recommendations for a specified age range).

Individual Nutrient Level 98 (INL98)² is the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.

² Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

Upper Level of Intake (UL)³ is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

Acceptable Macronutrient Distribution Range (AMDR) is a range of intakes for a particular energy source that is associated with reduced risk of diet-related non-communicable diseases while providing adequate intakes of essential nutrients. For macronutrients, they are generally expressed as a percentage of energy intake.

Other than FAO and/or WHO (FAO/WHO), a Recognized Authoritative Scientific Body (RASB) as used in these Principles refers to an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, scientific and authoritative advice on daily intake reference values through primary evaluation** of the scientific evidence upon request and for which such advice is recognized through its use in the development of policies in one or more countries.

* In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

** Primary evaluation involves a review and interpretation of the scientific evidence to develop daily intake reference values, rather than the adoption of advice from another RASB.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs

3.1 Selection of suitable data sources to establish NRVs

Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs.

Relevant daily intake reference values that reflect recent independent review of the science, from recognized authoritative scientific bodies could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.

The daily intake reference values should reflect intake recommendations for the general population. CXG 2-1985 10

³ Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.

3.2 Selection of Nutrients and Appropriate Basis for NRVs

3.2.1 Selection of Nutrients and Appropriate Basis for NRVs-R

The NRVs-R should be based on Individual Nutrient Level 98 (INL98). In certain cases where there is an absence of, or an older, established INL98 for a nutrient for a specific sub-group(s), it may be more appropriate to consider the use of other daily intake reference values or ranges that have been more recently established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

The general population NRVs-R should be determined by calculating the mean values for a chosen reference population group older than 36 months. NRVs-R derived by the Codex Alimentarius Commission are based on the widest applicable age range for each of adult males and females.

For the purpose of establishing these NRVs-R, the values for pregnant and lactating women should be excluded.

3.2.2 Selection of Nutrients and Appropriate Basis for NRVs-NCD

The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:

- Relevant convincing⁴/ generally accepted⁵ scientific evidence or the comparable level of evidence under the GRADE classification⁶ for the relationship between a nutrient and non-communicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g. adults).
- Public health importance of the nutrient-non-communicable disease risk relationship(s) among Codex member countries.

Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available in order to determine an NRV-NCD that is applicable to the general population.

Daily intake reference values from FAO/WHO or recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.

⁴ At the time these guiding principles were drafted, the definition and criteria for "convincing evidence" from the following FAO/WHO report were used Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916. WHO, 2003.

⁵ For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

⁶ WHO's Guidelines Review Committee. WHO Handbook for guideline development. Geneva, World Health Organization (WHO), 2014 (http://www.who.int/kms/handbook_2nd_ed.pdf)

For practical application in nutrition labelling, a single NRV-NCD for the general population should be established for each nutrient that meets the principles and criteria in this Annex.

An NRV-NCD for the general population should be determined from the daily intake reference value for the general population or adults, or if given by sex, the mean of adult males and adult females.

Where a daily intake reference value is based on a percentage energy intake, the single NRV-NCD should be expressed in grams or milligrams based on a reference intake for the general population of 8 370 kilojoules/2000 kilocalories.

Governments may use a Codex NRV-NCD based on the reference energy intake of 8 370 kilojoules/2 000 kilocalories, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region.

3.3 Consideration of Daily Intake Reference Values for Upper Levels

The establishment of general population NRVs should also take into account daily intake reference values for upper levels established by FAO/WHO or recognized authoritative scientific bodies where applicable (e.g. Upper Level of Intake, Acceptable Macronutrient Distribution Range).



Nutrient reference values (NRVs) are derived from authoritative recommendations for daily nutrient intake and form part of the information on a food label to guide consumers in making food choices. The Codex Committee for Nutrition and Foods for Special Dietary Uses worked over several years to develop Codex NRVs for the essential nutrients: protein, vitamins and minerals in the Codex Guidelines for Nutrition Labelling. The guidelines play a key role for governments when they wish to develop or update their national regulations and harmonise with international standards. This publication documents the process and decisions involved in reviewing the Codex NRVs and provides a valuable record of many years of novel and complex technical work.

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