Dietary Reference Intakes for Japanese (2015)

Ministry of Health, Labour and Welfare

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I Development and Application

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# **Development and Application**

of Dietary Reference Intakes for Japanese

# 1. Introduction

*The Dietary Reference Intakes for Japanese* proposes reference values for the intake of energy and nutrients, in the Japanese population, comprising both healthy individuals and groups, for the promotion and maintenance of health, and to prevent the occurrence of lifestyle-related diseases (LRDs).

The objectives behind the development of the *Dietary Reference Intakes for Japanese* (2015) are shown in Figure 1. The formulation of the dietary reference intakes (DRIs) employed the basic concepts of Health Japan 21 (second term)--a national health program initiated in 2013--based on the progression of aging and increase in the prevalence of diabetes and other diseases. The DRIs were developed to prevent the onset and progression of LRDs, as well as to maintain and promote health. To achieve these goals, the DRIs were determined in coordination with the guidelines for various other related diseases too.

The DRIs were determined based on scientific findings, the data of which were available. If some issues were deemed important, and yet no sufficient corresponding scientific data were available, these research topics were summarized and organized.

# 1-1. Target Individuals and Groups

The DRIs are intended for use by healthy individuals and groups, including individuals leading independent daily lives, despite having a risk of hypertension, dyslipidemia, hyperglycemia, and chronic kidney disease. They are aimed, specifically, at those who are able to participate in normal physical activities, such as walking or performing household tasks, and those with a body mass index (BMI\*) that does not deviate markedly from the standard. The inclusion range of individuals with the risk of the above-stated diseases are the level of "receiving health guidance." For the treatment of individuals and groups with diseases, or who are at a high risk for a certain disease, nutritional management is implemented under the treatment guidelines for the disease in question, on the basis of an understanding of the basic concept of energy and nutrient intake, in the DRIs.

\*BMI = body weight (kg)  $\div$  (height [m])<sup>2</sup>

# 1-2. Targeted Energy and Nutrients for the Development of the DRIs

The DRIs for energy and nutrients, as presented in Figure 2, were determined on the basis of the Health Promotion Act. Additionally, the nutrient intake, essential to health maintenance and promotion, was examined quantitatively, and the presence of nutrients, which can scientifically be deemed sufficiently reliable, was also investigated.

#### Figure 1. Dietary Reference Intakes Determined on the Basis of the Health Promotion Act

1. Matters regarding the desired <u>amount of calories</u> citizens should consume to maintain and promote their health.

2. Matters regarding the optimal consumption of the following <u>nutrients</u>, for the maintenance and promotion of health:

- (a) Nutrients, the <u>deficiency</u> of which, as stipulated by an ordinance of the Ministry of Health, Labour and Welfare, affects <u>citizens' health maintenance and promotion</u>, from the standpoint of the current nutrient intake status
  - Proteins
  - n-6 fatty acids and n-3 fatty acids
  - Carbohydrates and dietary fiber
  - Vitamin A, vitamin D, vitamin E, vitamin K, vitamin  $B_1$ , vitamin  $B_2$ , niacin, vitamin  $B_6$ , vitamin  $B_{12}$ , folic acid, pantothenic acid, biotin, and vitamin C
  - Potassium, calcium, magnesium, phosphorus, iron, zinc, copper, manganese, iodine selenium, chromium, and molybdenum
- (b) Nutrients, the deficiency of which, as stipulated by an ordinance of the Ministry of Health, Labour and Welfare, affects <u>citizens' health maintenance and promotion</u>, from the standpoint of the nutrient intake status
  - Fat, saturated fatty acids, and cholesterol
  - Sugars (limited to monosaccharides or disaccharides and non-sugar alcohols)
  - Sodium

# 1-3. Purposes and Types of Reference Values

# • Energy

For energy, reference values were set to avoid excessive or deficient intakes.

# • Nutrients

For nutrients, the DRIs have five types of values designed for three purposes: avoiding inadequacy, avoiding adverse health effects due to excessive intake, and preventing LRDs (Figure 2).

To prevent inadequate intake, the estimated average requirement (EAR) was determined. The EAR is the intake amount that would meet the nutrient requirements of 50% of the population. The recommended dietary allowance (RDA) was determined to supplement the EAR. The RDA is the intake amount that would meet the requirements of most of the population.

The adequate intake (AI) was developed for cases in which the EAR and RDA could not be set, due to insufficient scientific evidence. The AI indicates the intake amount that is adequate to maintain a certain nutritional status. Having dietary intakes that are no less than the AI minimize the risk of inadequacy.

To avoid adverse health effects due to excessive intake, the tolerable upper intake level (UL) was determined. No ULs were set for the nutrients for which there was insufficient scientific evidence.

The DRIs for several nutrients need to be established, for the prevention of LRDs. However, the research focusing on those nutrients is not sufficient, both quantitatively and qualitatively<sup>(1)</sup>. Therefore, tentative dietary goals (DGs) for the prevention of LRDs, were determined as "the nutrient intake amount Japanese people should aim for, to prevent LRDs, in the foreseeable future."



Figure 2. Purposes and types of nutrition indices

# 1-4. Classification of Age

Age was classified based on the *Dietary Reference Intakes for Japanese (2010)*. Infants were divided into two groups: 0–5 months and 6–11 months. When the inclusion of more detailed age group settings was deemed necessary, particularly in accordance with growth, three age groups were set: 0–5 months, 6–8 months, and 9–11 months.

Individuals aged 1–17 years were considered children, and those over 18 years of age were considered adults. When it was deemed necessary for elderly individuals to be differentiated from other adults, those above the age of 70 years were termed "elderly". Cases in which the setting of more detailed age groups was necessary, for elderly adults, were also examined.

#### 2. Basics of Development

#### 2-1. Overview of the Indices

#### 2-1-1. Energy

BMI was adopted as an index to indicate the state of maintenance of the balance between energy intake and consumption (energy balance). The target BMI range was, therefore, presented after the comprehensive verification of the BMI range, with the lowest all-cause mortality reported in epidemiological observational studies in adults, and the current BMI status of Japanese people. However, BMI should be treated merely as a factor associated with the maintenance and promotion of health, prevention of LRDs, and avoidance of physical weakness due to old age.

Since there are several non-negligible interindividual differences that influence energy requirement, it is difficult to present energy requirement as a single value, according to sex, age group, and level of physical activity. However, the concept of energy requirement is important, and the target BMI is limited to adults. Moreover, an approximated energy requirement would be necessary to calculate the EAR of the nutrients that are known to depend on energy requirement. Therefore, the estimated energy requirement (EER) was set as a reference value, describing energy requirements and estimation methods.

#### 2-1-2. Nutrients

#### • Estimated Average Requirement (EAR)

The EAR is the average daily nutrient intake level required in a population (e.g., 30–49-year-old men), calculated on the basis of the distribution of the measured requirements in a study population. In other words, the EAR is effectively defined as the estimated intake amount that meets the requirements of 50% of the individuals belonging to an age or sex group; in the remaining 50% of the population, the intake requirement is not met.

The EAR is the primary reference point for the avoidance of inadequacy, but "inadequacy" here does not just mean deficiency in the conventional sense; its definition differs depending on the nutrients.

#### • Recommended Dietary Allowance (RDA)

The RDA is an estimate of the daily average dietary intake that satisfies the needs of most of the individuals belonging to a population (97–98%), on the basis of the distribution of the measured requirements of a study population. The RDA is set for nutrients for which the EAR is available, and is calculated using the EAR.

The RDA is theoretically calculated as "the EAR  $+ 2 \times$  standard deviations (SDs)", using the SD of the interindividual variability in the requirements, observed in the experiments, as the estimated SD of the interindividual variability in the requirements of a population. However, since it is difficult to obtain an accurate SD of the EAR from experiments, often, estimates have to be used.

The RDA is, therefore, obtained by the following equation:

 $RDA = EAR \times (1 + 2 \times coefficient of variation) = EAR \times RDA$  calculating coefficient

#### • Adequate Intake (AI)

If sufficient or adequate scientific evidence is not available to establish the EAR and, thus, the RDA, the AI is set for the nutrients. The AI is the intake level recommended for the sufficient maintenance of nutritional status in a specific population. In reality, AI is described as the presence of an adequate nutritional state in most individuals of a specific population. It is obtained from epidemiological studies that observe nutrient intake in a large number of healthy individuals.

AI is set based on any of the three following concepts:

- (1) When the AI is based on the biomarkers for health status and nutrient intake, in a specific population, the intake amount associated with the least deficiency is used. In this case, the median of the nutrient intakes is used.
- (2) When health status cannot be confirmed using biomarkers, but the distribution of the typical nutrient intake of a population, composed primarily of healthy Japanese people can be obtained, the median nutrient intake is used.
- (3) When the AI is based on the intake of healthy infants raised on breast milk, the nutrient concentration of breast milk and the suckled milk volume are used for the calculation.

The concept utilized for the determination of the AI depends on the nutrient, sex, and age group.

#### • Tolerable Upper Intake Level (UL)

The UL is the highest average daily nutrient intake level that is not likely to pose any risk of adverse health effects. As the intake exceeds the UL, the potential risk of adverse health effects may increase.

The UL theoretically exists between the maximum "average daily intake known not to cause adverse health effects" (no observed adverse effect level: NOAEL) and the minimum "average daily intake known to cause adverse health effects" (lowest observed adverse effect level: LOAEL). However, there are few reports on this subject, and those that examine specific populations are limited. Furthermore, the NOAEL and LOAEL have to be obtained on the basis of the results of experiments conducted under artificially constructed conditions, such as animal and *in vitro* experiments, in some cases. The UL was, therefore, set as the NOAEL or LOAEL, divided by uncertainty factors (UF), to ensure the safety in dietary intake considering the uncertainty of the obtained value. More specifically, the UL was calculated as follows:

• When the UL was calculated using data of the consumption of regular food in humans: UL = NOAEL  $\div$  UF (the appropriate value in the range of 1–5 was used as the UF) • When the UL was calculated using data of the consumption of supplements, in humans, or of animal and *in vitro* experiments:

 $UL = LOAEL \div UF$  (10 is used as the UF)

#### • Tentative Dietary Goals for Preventing Lifestyle-Related Diseases (DG)

The DGs required for the prevention of LRDs were set as the current goals for Japanese individuals to reach the average daily intake of nutrients, and, thereby, prevent LRDs. DGs were calculated as the average daily intake required to achieve a nutritional status in a specific population in which the value of the biomarkers (proxy indicators), and risk of disease are considered low. Further, they were developed taking into account the findings of experimental nutritional studies, including findings primarily obtained from epidemiological studies. However, the association between nutrient intake and the risk of LRDs is continual, and there is often no threshold. In such cases, it is difficult to propose a value or range for the desired nutrient intake. DGs were, therefore, set with an emphasis on feasibility, taking into account the DRIs and disease prevention guidelines of other countries as well as current Japanese nutrient intakes, food compositions, preferences, etc.

The following three calculation methods were used when considering the characteristics of each nutrient:

• When the current nutrient intake of Japanese people was lower than the desired intake, only the values below the range were calculated. This applied to dietary fiber and potassium. Considering feasibility, the median of the desired nutrient intake and current nutrient intake was used for these values. The same extrapolation method as that used for AI (using reference body weight) was used for children. However, in the event that the nutrient intake calculated with this method was greater than the median of the current nutrient intake, the latter was set as the DG.

• When the current nutrient intake of Japanese people was greater than the desired nutrient intake, only the values above the range were calculated. This applied to saturated fatty acids and sodium (salt equivalent). These values were calculated taking into account recent trends in nutrient intake and feasibility in achieving the desired intake level. Sodium (salt equivalent) intake, in children, was extrapolated using EERs, and calculated taking into account the feasibility.

• As a composite indicator of the prevention of LRDs, in the present DRIs, for the energyproviding nutrients' balance (the proportion of proteins, lipids, and carbohydrates [including alcohol]), the total energy intake percentage was calculated.

#### 2-2. Review Methods

The present DRIs were developed on the basis of scientific evidence, wherever possible. Scientific papers, both from Japan and other countries, and other available academic material, were systematically reviewed.

In a basic review of the issues pertaining to energy and nutrients, emphasis was placed on the problems associated with the development of the *Dietary Reference Intakes (2010)*. At the same time, the target characteristics of the elderly individuals and infants were intensively reviewed. The Patient-Intervention-Comparison-Outcome (PICO) format was used to review the relationship between energy/nutrients, and the prevention of LRD onset and progression, in order to formulate research questions on hypertension, dyslipidemia, hyperglycemia, and chronic kidney diseases. In addition to these diseases, a limited review was conducted on other diseases, if the quantitative relationship with other nutrient intakes was elucidated by a number of studies, and the disease was considered important for Japanese people. On this occasion, the review paid attention to the health status and severity classification of the research participants. These reviews were primarily conducted under the "Study on Nutritional Assessments of Metabolic Disorders that Contribute to Dietary Reference Intakes for Japanese," funded by a 2013 Ministry of Health, Labour and Welfare Grant-in-Aid for Scientific Research (Comprehensive Project to Prevent Lifestyle-related Diseases such as Cardiovascular Disease and Diabetes). This review method will need to be standardized in the future.

Moreover, the papers and materials used in the previous development of DRIs were also reviewed as needed. However, unlike in other medical fields, the methods of determining and proving the evidence level have not been sufficiently established in the fields of Human Nutrition, Public Nutrition, and Preventive Nutrition. Furthermore, variations can occur in the obtained evidence level between nutrients.

Considering the above circumstances, when information had been quantitatively integrated, such as in the case of meta-analyses, the DRIs preferentially referred to this quantitatively integrated information. In reality, the content of each study was thoroughly examined, and the most reliable information available at that time was used.

#### 2-3. Adoption Policies for the Revisions of the DRIs

#### • Estimated Average Requirement

• When sufficient scientific evidence was obtained for nutrients, the EARs of which were not available, the EAR was newly determined.

• When the physical endpoints were changed in the EAR calculations, the value for the EAR was changed in accordance with the evidence.

• The EAR value was changed, as needed, with changes in the reference body size.

#### • Recommended Dietary Allowance

• When the EAR was newly set or changed, the RDA was newly set or changed, accordingly.

• When the coefficient of variation was changed, the RDA was changed.

<Condition necessary to change the coefficient of variation>

When clear evidence, deemed necessary to change the coefficient of variation, can be obtained.

# • Adequate Intake

• When the distribution of the typical nutrient intakes of Japanese people was obtained for a population, which comprised very few individuals with nutrient inadequacy, the median was set as the AI. In such cases, the use of the median of the population with the lowest intake, as obtained from several reports, was recommended.

Moreover, when developing the AI, it is necessary to pay attention to the extent of "sufficient amount," that does not indicate nutrient inadequacy. Therefore, it was handled as follows:

(1) When the AI could be determined based on the DRIs of other countries, international guidelines, survey data, etc., the appropriate value was selected regardless of the median.

(2) When the extent of "sufficient amount" was difficult to determine, it was permissible to select the median of the obtained data after describing the sufficient amount.

# • Tolerable Upper Intake Level

- When sufficient scientific evidence was available, the UL was newly set.
- When the need to review the incidence of adverse health effects arose, as a result of new knowledge, the UL was changed.
- When new knowledge requiring a change of the UL was obtained in the process of determining the UFs, the UFs were changed.

# • Tentative Dietary Goals for Preventing Lifestyle-related Diseases

- The presence of sufficient scientific evidence for the setting of values, combined with the higher priority given to the relationship between dietary intake and LRDs in the current Japanese population, required the DGs to be newly set.
- When the values derived from sufficient scientific evidence deviated greatly from the actual dietary intakes of citizens, the DGs were set with the current dietary intake as the target amount.

#### 2-4. Age Classification

The age classification was similar to that used in the Table 1. Age Classification previous DRIs (Table 1.). Infants were divided into two groups: 0-5 months, and 6-11 months. Energy and proteins, which were thought to require a more detailed categorization of age groups, particularly in accordance with growth, were presented in three age groups: 0–5 months, 6–8 months, and 9–11 months.

From ages 1-17 years, individuals were considered children, and from the age of 18 years, adults. When there was a need for elderly individuals to be differentiated from other adults, those aged 70 years or older were described as "elderly". Furthermore, for those aged 70 years or older, attention was paid to the age range in the literature that served as evidence for the development of the DRIs, and the age range was specified as needed. In light of the increase in the proportion of the elderly population, in Japan, a detailed age classification may need to be

formulated for the elderly; however, this should be the topic of future study, as enough evidence has not been obtained at this time.

#### 2-5. Reference Body Size (Reference Height and Reference Weight)

#### 2-5-1. Purpose

The body size (height and body weight) referenced in the development of the present DRIs was assumed to be the average Japanese body size, according to sex and age. This was referred to as the reference body size (reference height and body weight; Table 2). Previously, this value was referred to as the "standard body size"; however, the expression was revised to "reference body size" as it refers to the average Japanese body size, but not the desired body size.

Age		
0-5 (months)*		
6-11 (months)*		
1-2 (years)		
3-5 (years)		
6-7 (years)		
8-9 (years)		
10-11 (years)		
12-14 (years)		
15-17 (years)		
18-29 (years)		
30-49 (years)		
50-69 (years)		
70 years or older		

<sup>\*</sup> For energy and protein, these age categories were classified into 0-5, 6-8, and 9-11 months old.

Gender	Male		Female	
A == (	Reference	Reference	Reference	Reference
Age (years)	Height (cm)	Weight (kg)	Height (cm)	Weight (kg)
0-5(months)	61.5	6.3	60.1	5.9
6-11(months)	71.6	8.8	70.2	8.1
6-8(months)	69.8	8.4	68.3	7.8
9-11(months)	73.2	9.1	71.9	8.4
1-2 (years)	85.8	11.5	84.6	11.0
3-5 (years)	103.6	16.5	103.2	16.1
6-7 (years)	119.5	22.2	118.3	21.9
8-9 (years)	130.4	28.0	130.4	27.4
10-11 (years)	142.0	35.6	144.0	36.3
12-14 (years)	160.5	49.0	155.1	47.5
15-17 (years)	170.1	59.7	157.7	51.9
18-29 (years)	170.3	63.2	158.0	50.0
30-49 (years)	170.7	68.5	158.0	53.1
50-69 (years)	166.6	65.3	153.5	53.0
70 years or older	160.8	60.0	148.0	49.5

 Table 2.
 Reference Body Size (Reference Height and Reference Weight)

#### 2-5-2. Basic Concept

The standard height and body weight values, used in the assessment of children's body sizes, by the joint committee on growth reference value, The Japanese Society for Pediatric Endocrinology and the Japanese Association for Human Auxology, were used as the reference body sizes of infants and children<sup>(2)</sup>.

Meanwhile, the ideal standard body size in adults, according to sex and age group, is yet to be revealed. Therefore, based on the policies of the Dietary Reference Intakes for Japanese (2005 and 2010), the most recent data available were used as the current values for the calculation of a representative value for each sex and age group.

Currently, the prevalence of overweight for Japanese men is approximately 30%, while that of underweight for Japanese women aged 20–30 years is approximately 20%. Furthermore, there are problems associated with height and weight measurements in elderly individuals. The ideal body size needs to be verified on the basis of these facts in the future.

#### 2-5-3. Calculations Methods

# • Infants and Children

The median values of the relevant age groups, in months and years, were cited on the basis of the standard values for height and weight used in the assessment of children's body

sizes by the joint committee on growth reference value, The Japanese Society for Pediatric Endocrinology and the Japanese Association for Human Auxology<sup>(2)</sup>.

# • Adults (18 Years and Older)

The median for the height and weight of each relevant sex and age group in the 2010 and 2011 National Health and Nutrition Survey was used. Pregnant and lactating women were excluded from the calculation. The following statistics, showing the distribution, were used as reference material (Supplemental Tables 1 and 2).

	<b>A</b> ()	Percentile		
	Age (years)	25	50	75
	18-29	167.0	170.3	175.0
Mala	30-49	167.0	170.7	175.0
Male	50-69	162.7	166.6	170.5
	70 years or older	157.2	160.8	165.2
	18-29	154.4	158.0	161.5
Female	30-49	154.5	158.0	161.3
	50-69	150.0	153.5	157.0
	70 years or older	143.3	148.0	152.0

Supplemental Table 1. The distribution of body height (25, 50, 75 percentile)

Supplemental Table 1.	The distribution of bod	v weight (25, 50, 75	nercentile)
Supplemental Table I.	The distribution of bod	j	per centite)

Age (years)		Percentile		
		25	50	75
	18-29	57.0	63.2	70.8
Male	30-49	62.0	68.5	76.2
	50-69	60.0	65.3	72.2
	70 years or older	53.9	60.0	66.2
	18-29	46.1	50.0	55.0
Female	30-49	48.0	53.1	59.3
	50-69	48.0	53.0	58.6
	70 years or older	43.8	49.5	55.1

#### 3. Considerations for Development

#### 3-1. Intake Sources

The energy and nutrients in consumed foods were examined. Intake from the diet was used for calculation; however, apart from regular food, the energy and nutrients contained in foods consumed for health promotion and not intended for the treatment of disease were also examined. These include so-called health drinks, nutritional supplements, foods with fortified nutrients (fortified food), foods for specified health uses, foods with nutrient function claims, and so-called health foods and supplements. However, the UL of folic acid was set for intake only from sources other than regular food.

#### 3-2. Intake Period

The DRIs provide references for habitual intake, and are expressed in units *per day*; they do not present references for short-term diet (e.g., for 1 day). This is because nutrient intake varies greatly from day to  $day^{(3-6)}$ , and the adverse health effects discussed in the DRIs occur as a result of the habitual excess or inadequate intake of energy and nutrients.

The time required for the adverse health effects associated with the inadequate or excess intake of nutrients to manifest varies greatly, depending on the type of nutrient and adverse health effect. For example, consuming a diet almost completely devoid of vitamin  $B_1$  can result in a large decrease in serum vitamin  $B_1$  levels after 2 weeks, with various vitamin  $B_1$  deficiency symptoms manifesting within 4 weeks<sup>(7)</sup>, indicating the need for nutritional management within 1 month. In contrast, one report noted a relationship between the excessive intake of sodium (salt) and age-related increases in blood pressure<sup>(8)</sup>, suggesting the importance of nutritional management over several decades. The time required for adverse health effects to develop or improve varies greatly depending on the type of nutrient and adverse health effect.

It is difficult to specifically show a certain habitual intake period, from the viewpoint of the intake characteristics of energy and nutrients, i.e., day-to-day variations. According to results of studies that very broadly observed the day-to-day variations in energy and nutrient intake<sup>6–8</sup>, the time required to understand or manage habitual intake is approximately "1 month," excluding some nutrients with very large day-to-day variations, allowing for some degree of measurement error and interindividual differences.

#### 3-3. Intake Frequency and Ratio, and Speed of Eating

The frequency of consuming meals, throughout the day, particularly pertaining to whether or not breakfast is consumed, has been reported to contribute to the incidence of diseases such as obesity and cardiovascular disease<sup>(9)</sup>. Moreover, differences in the intake ratios of energy and nutrients between meals throughout the day have been reported to have an effect on the development of metabolic syndrome<sup>(10)</sup>. Some studies have also reported the association between the differences in time zones and nutrient intake<sup>(11)</sup>. These reports suggest the likely involvement of energy, nutrient intake, and metabolism in human biological circadian rhythms,

as well as an association of deviations between circadian and daily life rhythms with energy and nutrient metabolism<sup>(12)</sup>. Furthermore, some reports claim that intake speed is involved in the development of obesity, metabolic syndrome, and diabetes<sup>(13)(14)(15)(16)(17)</sup>. These reports focus more on the physiological effects of intake timing and speed on the body rather than habitual energy and nutrient intake. However, dietary intake in daily life is also influenced by external factors, in addition to biological circadian rhythms, suggesting the need for further basic research and epidemiological studies.

# 3-4. Handling Research Data

# • Data on the Nutrient Intake Status of Japanese People

Exemplary scientific papers describing the nutrient intake status of Japanese people were cited, and when there was a lack of appropriate data, values based on data from the most recent National Health and Nutrition Survey were cited.

Importantly, it has been revealed that there are underreported findings in most dietary survey methods, including dietary records. However, it remains unclear to what extent the National Health and Nutrition Survey underestimates nutrient intake. This issue needs to be verified in the future.

# • Methods of Integrating Research Results

To integrate research results, the policy presented in Table 3 was determined.

Quality of the studies	Are there any studies examining Japanese people?	To integrate the studies' results:
	Yes	Use the results of the Japanese studies preferentially
Relatively homogeneous	No	Use the average value of the total results of the studies
	Yes; the study's quality is high	Use the results of the Japanese studies preferentially
Largely different between studies	Yes; but the study's quality is relatively low	Chose the studies with high-quality and use the average value of these studies' results

Table 3. Basic policy to integrate research results

# • Handling Interventional Studies Using Supplements and Other Food Sources

A few nutrients are expected to prevent the occurrence of some LRDs if consumed in quantities that markedly exceed the amount that can be consumed from regular foods. In order to verify those effects, interventional studies using supplements are sometimes conducted. However, it was reported that undesirable health effects might arise after a certain favorable effect<sup>(18)</sup>. A prudent stance should, therefore, be taken in validating the consumption of large quantities of specific nutrients from sources other than regular food (such as supplements).

Therefore, the present DRIs did not include data from studies using quantities of specific nutrients that were deemed clearly impossible to consume in combination with regular food (excluding supplements). However, these studies were also reviewed for use as reference material, in the determination of the DRIs.

#### **3-5.** Extrapolation Methods

#### • Basic Concept

The values employed in calculating the five types of reference values (EAR, RDA, AI, UL, and DG) used in the DRIs were observed in individuals limited to a certain sex and age. Values, therefore, need to be extrapolated from these reference values to determine the DRIs, according to sex and age group.

The reference values for EAR and AI are often obtained from daily intakes (weight/day), whereas the reference values for UL are often obtained from intake per kg of body weight (weight/kg, body weight/day). Therefore, extrapolation methods were determined for each type of values.

For the RDA, the EAR was extrapolated from the reference EAR, according to sex and age group, and then each extrapolated EAR was multiplied by the RDA calculation coefficient. For DG, the AI was first extrapolated from the AI reference values, according to sex and age group, and then each extrapolated AI and the median nutrient intake of each sex and age group was used to set the DG for each sex and age group.

#### • Estimate Average Requirement and Adequate Intake

It is difficult to determine extrapolation methods that take into account the characteristics of nutrients. Therefore, focusing on the strong relationship between energy metabolic efficiency and body surface area, the body surface area estimated from height and/or body weight is widely used in extrapolation<sup>(19)</sup>. Several formulas, for the estimation of body surface area from height and/or body weight, have been proposed. In the present DRIs, a method using a body weight ratio to the 0.75 power, proposed in 1947, was adopted<sup>(20)</sup>. This method has recently been examined in greater detail, and is reportedly useful in estimating the organ weight of various organisms, including mammalian cardiovascular and respiratory organs<sup>(21)</sup>.

The following approaches were used for adults and children:

When the reference value for the EAR or AI was given as the amount of intake per day (weight/day), and the representing value of body weight of the target population is clear in the study from which the reference value was obtained, the reference value was extrapolated as follows:

#### X: X0 × (W/W0) $0.75 \times (1 + G)$

X: The sought EAR or AI of the age group (intake per day)

X0: The EAR or AI reference value (intake per day)

W: The sought reference body weight of the age group

W0: Typical body weight of the participants in the study from which the reference value for the EAR or AI was obtained (mean or median)

G: Growth factor (value determined based on Table 4)

Depending on the studies, the EAR or AI reference value may sometimes be given per kg of body weight. In such instances, the reference value was extrapolated as follows:

#### $\mathbf{X} = \mathbf{X}\mathbf{0} \times \mathbf{W} \times (\mathbf{1} + \mathbf{G})$

X: The sought EAR or AI of the age group (intake per day)

X0: The EAR or AI reference value (intake per kg of body weight)

W: The sought reference body weight of the age group

G: Growth factor (value determined based on Table 4)

In the case of children, it is necessary to take into account the amount utilized for growth, and the amount accumulated in the body, in association with growth. Thus, the values adopted by the FAO/WHO/UNU<sup>(22)</sup> and the *US–Canada Dietary Reference Intakes*<sup>(19)</sup>, as growth factors, were modified to suit Japanese age groups and used in the present DRIs (Table 4).

Age	Growth Factor
6-11 (months)	0.30
1-2 (years)	0.30
3-14 (years)	0.15
15-17 (years) (male)	0.15
15-17 (years) (female)	0
18 years or older	0

Table 4. Growth factors used to estimate EAR or AI

In 6–11-month-old infants, there are two ways in which values can be extrapolated: 1) extrapolating from the values of 0–5-month-old infants; and 2) adopting the median of 0–5-month-old infants and the median of 1–2-year-old infants.

When extrapolating values from the DRIs of 0–5-month-old infants, the following formula has been proposed<sup>(19)</sup>.

(Body weight of the reference body size of 6–11-month-old infants  $\div$  body weight of the reference body size of 0–5-month-old infants)<sup>0.75</sup>

However, this formula does not take into account growth factors, because 0–5-monthold infants are still undergoing growth, and components attributable to growth factors are included in their DRIs. If the reference body weight is substituted, the formulas for men and women are  $(8.8 / 6.4)^{0.75}$  and  $(8.2 / 5.9)^{0.75}$ , respectively, producing respective reference values of 1.27 and 1.28. This formula provides an extrapolated value that varies slightly between men and women, so the mean of the extrapolated values for men and women is used as the AI for both men and women.

Some nutrients are extrapolated using other methods, taking into account nutrient characteristics and available data, such as the following:

• Calculations based on nutrient intake from breast milk and intake from sources other than breast milk

The following formula was used:

# Nutrient concentration of breast milk × average milk intake + intake from sources other than breast milk

· Calculations from values extrapolated from the DRIs for 0-5-month-old infants and 18-29-

#### year-old adults

This is how the mean of the values extrapolated using these two methods was set as the AI, and this method was used for water-soluble vitamins. Specifically, the reference values for the AI of 0–6-month-old infants was calculated independently from those of the AI of 0–5-month-old infants and the EAR (or AI) of 18–29-year-old adults. The values obtained for men and women were then averaged, and the same value was set for both. This value was rounded to obtain a common AI for men and women. Extrapolation was performed using the following method:

• Extrapolation from the AI of 0-5-month-old infants

(AI of 0–5-month-old infants) × (reference body weight of 6–11-month-old infants  $\div$  reference body weight of 0–5-month-old infants)<sup>0.75</sup>

• Extrapolation from the EAR (or AI) of 18-29-year-old adults

(EAR [or AI] of 18–29-year-old adults) × (reference body weight of 6–11-month-old infants  $\div$  reference body weight of 18–29-year-old adults)<sup>0.75</sup> × (1 + growth factor)

A value of 0.30 was used for growth factors, based on the values adopted by the FAO/WHO/UNU and the *US–Canada Dietary Reference Intakes* (Table 4).

# • Tolerable Upper Intake Level

As with the EAR and AI, no theoretical and sufficiently reliable extrapolation method exists for UL. Reference values were, therefore, calculated for age groups with insufficient evidence, using one of the following methods:

When the reference value for UL was calculated, per kg of body weight, the following formula was used:

# $\mathbf{X} = \mathbf{X}\mathbf{0} \times \mathbf{W}$

X: The sought UL of the age group (intake per day)

X0: UL reference value (intake per kg of body weight)

W: The sought body weight of the reference body size of the age group

When the reference value for the UL was calculated, per day, the following formula was used.

# $\mathbf{X} = \mathbf{X0} \times (\mathbf{W}/\mathbf{W0})$

X: The sought UL of the age group (intake per day)

X0: UL reference value (intake per kg of body weight)

W: The sought body weight of the reference body size of the age group

W0: Typical body weight of the participants in the study from which the reference value for the UL was obtained (mean or median)

# **3-6.** Rounding Values

The EAR, RDA, AI, UL, and DG values were rounded, in accordance with the rules shown in Table 5, taking into account the reliability and convenience of the reference values. A single rule was applied to the reference value of each nutrient for both men and women, in the child, adult, and elderly individual age groups. The same display digit numbers were used in the additional amounts for infants, pregnant women, and lactating women as those used in the values of the other sex and age groups. After rounding, the values were smoothened, as needed, to prevent large discrepancies between the age groups.

# 4. Application of the DRIs

# 4-1. Basic Concept

The application of the DRIs to the dietary modification of healthy individuals and groups, for the purpose of health maintenance and promotion and prevention of LRDs, is based on the concept of the PDCA cycle (Figure 3). First, an assessment of dietary intake status is conducted to determine if the energy and nutrient intake are sufficient. Based on this, intake is improved through the formulation of a dietary improvement plan. Subsequently, results are evaluated, including a dietary assessment. Lastly, the plan and its content are improved upon, on the basis of the results of these evaluations.



Figure 3. Application of Dietary Reference Intakes and PDCA cycle

# 4-2. Methods of Assessing Dietary Intake

# • Applying DRIs and Assessing Dietary Intake

Dietary intake, i.e., intake of energy and nutrients, can be assessed by comparing each of the values in the DRIs with the results obtained from the dietary assessment. To assess excessive or inadequate energy intake, the BMI or amount of change in the body weight should be used.

The intake amounts obtained from dietary assessments are accompanied by measurement errors. To ensure a higher level of accuracy, sufficient consideration should be given to their standardization and accuracy control. The types, characteristics, and degrees of dietary assessment measurement errors need to be considered when dietary intake is assessed. Particularly, attention must be paid to measurements errors such as under- and overreporting, and day-to-day variations.

When energy and nutrient intakes are estimated from dietary assessments, nutritional

values are calculated using food composition tables. However, the nutrient quantities in food composition tables, and the nutrient quantities contained in the actual foods consumed are not necessarily the same. Nutrient calculations, therefore, need to be performed with an understanding of such errors.

Additionally, to assess whether the energy and nutrient intake amount is appropriate, it is necessary to conduct a comprehensive assessment of the target individuals, including clinical symptoms and laboratory test values, and factors such as their living environments and lifestyle habits. It is important to note that clinical symptoms and laboratory test values are also influenced by factors other than the nutrient intake status in question. Figure 4 shows an overview of the application of the DRIs and assessment of dietary intake.



Figure 4. Applying DRIs and Assessing Dietary Intake

# • Dietary Assessment

Dietary intake can be assessed in several ways such as the duplicate diet method, meal recording method, dietary recall method, food frequency method, dietary history method, and the use of biomarkers. Each of the methods has its own advantages and disadvantages, and characteristics. It is important to select an appropriate method based on the circumstances and the purpose of the assessment.

The DRIs present reference values for habitual intakes. Therefore, for their application, methods that can estimate habitual intakes must be selected. However, it is quite difficult to obtain accurate data on long-term average nutrient intakes at the individual level. Taking this into account, the food frequency method and diet history method may prove more efficient in the estimation of habitual intakes, for the application of the DRIs to individuals or groups. However, as these methods do not convert consumed foods directly into data, it is necessary to verify their reliability (validity and reproducibility). It is, therefore, best to use a method that

has been internationally recognized in scientific studies published on reliability.

Additionally, for some nutrients, the intake estimation accuracy is low during the dietary assessment. In such cases, estimation methods that use biomarkers such as urinary concentration should also be considered.

#### 4-3. Note for Use of the DRIs

While the precautions associated with the use of each of the indices are described below, the method used differs depending on the purpose of the indices and the type of nutrients. Therefore, it is important to sufficiently understand the purpose of use, the definitions of the indices, and the characteristics of the nutrients.

# • Energy Balance

BMI is an index of energy intake, and consumption balance maintenance (energy balance). For all practical purposes, excessive or inadequate energy intake is assessed by measuring changes in body weight. Alternatively, a comprehensive assessment, including other factors, is performed to ascertain whether there is a risk of the measured BMI falling below the target BMI range--"deficiency"--or exceeding the target range--"excess." From the standpoint of preventing LRDs, it is recommended to address energy balance, with an emphasis on individual characteristics, based on the basic concept of body weight management and the desired BMI range (body weight), in each age group. To prevent the progression of LRDs, it is best to adjust the energy balance while assessing the rate of reduction of the body weight and improvement in the health status.

#### • Estimated Average Requirement

The EAR indicates a 50% probability of the presence of a deficiency. Since the EAR is assumed to be the nutrient intake level that half of the individuals of a group are estimated to be deficient in, if the intake level falls below this value or there are a number of individuals whose consumption levels fall below it, urgent action must be taken.

#### • Recommended Dietary Allowance

The RDA indicates almost no probability of the presence of deficiency in an individual, and at this consumption level, very few individuals in a population are assumed to be deficient. Therefore, when the consumption is close to or greater than this value, it is considered that there is almost no risk of deficiency.

#### Adequate Intake

An AI value is set when sufficient scientific evidence cannot be obtained. Therefore, it is a reference value that is established when the EAR cannot be calculated, and, thus, the risk of deficiency is extremely low if an individual consumes more than the AI. Consequently, there is almost no probability of deficiency when the amount of nutrients consumed is close to the AI, and almost no probability of deficiency in individuals in a group. In addition, the AI should be theoretically higher than the RDA, considering its definition. However, the presence or risk of deficiency cannot be indicated even if an individual's intake is less than the AI.

# • Tolerable Upper Intake Level

The occurrence risk of adverse health effects, due to excessive intake, is greater than zero in the event that an individual consumes more than the UL. However, it is very unlikely for an individual's consumption to exceed the UL, so long as he/she consumes regular food. Furthermore, it is very difficult to calculate the UL, both theoretically and experimentally, and most of the ULs are calculated on the basis of a small number of incidents. This demonstrates the lack of sufficient scientific evidence on the UL. This is why the UL is understood as "the amount that individuals should avoid approaching as much as possible" rather than "the amount that should not be exceeded."

The UL is also a value for adverse health effects caused by excessive intake, and is not set for the maintenance and promotion of health or prevention of LRDs. This needs to be fully considered when the UL is used.

#### • Tentative Dietary Goal for Preventing Lifestyle-related Diseases

The DG is a value calculated for the prevention of LRDs. LRDs have a variety of causes, and diet is only one factor. Therefore, from the standpoint of preventing LRDs, it is not sufficient to strictly follow the DG alone.

For example, the excessive intake of sodium (salt) is a risk factor for hypertension, so a DG is calculated for sodium (salt), primarily from this standpoint. However, hypertension has been reported to be associated with the excessive intake of alcohol and inadequate intake of potassium, as well as obesity and lack of exercise<sup>(23)</sup>. The DG for sodium (salt) should be determined with a sufficient understanding of the above issues, target individuals, and populations.

Furthermore, compared to adverse health effects caused by the inadequate or excessive intake of nutrients, LRDs occur as a result of lifestyle habits (including eating habits) continued over a very long period of time. Considering these characteristics of LRDs, long-term (e.g., lifelong) management is more important than short-term, intense management.

# 4-4. Note for Use According to the Purpose

# 4-4-1. Use in Improving the Diet of Individuals

The basic concept behind the use of the DRIs in improving the diet of individuals is presented in Figure 5.

The likelihood of inadequate or excessive intake is estimated by assessing the dietary intake status of individuals using the DRIs. On the basis of these results, the DRIs can be used to propose target values for appropriate energy and nutrient intakes in order to prevent inadequate and excessive intakes, as well as LRDs. These assessments should lead to the planning and implementation of dietary improvements.

Furthermore, in order to achieve a target BMI and nutrient intake level, nutrition education should be planned, implemented, and verified for improving the diet of individuals, such as through the development of effective tools and the provision of specific information on quantities and balance of dishes and food, as well as emphasizing the importance of increasing activity levels.



Figure 5. Basic concept for the use of the DRIs in improving the diet of individuals

# • Assessing Dietary Intake Status

An overview of the dietary intake status assessment, using the DRIs, to improve diet in individuals, is presented in Figure 6.

Individual intakes, obtained from dietary assessments, are used in this assessment; however, various factors influence daily intake, such as the different foods selected every day by an individual and differences in appetite, which makes understanding the habitual intakes of individuals challenging. This is why the assessed intakes of individuals include large measurement errors. They vary greatly from day to day; thus, it is important to understand that they do not reflect an individual's true intake.

Therefore, the assessment of dietary intake status should be performed using the DRIs, considering the above-stated limitations. Moreover, energy intake assessments are performed to evaluate whether the energy balance is positive or negative, and, for this purpose, BMI or change in body weight is used.



Figure 6. Assessing dietary intake status, using the DRIs, to improve the diet of individuals

BMI, or change in body weight, is used when assessing inadequate or excessive energy intake in adults. The target BMI range is presented in the present DRIs (See "Energy"). However, even if the BMI is within the target range, in the event that the body weight increases or decreases, careful and appropriate action is required, as this points to either a positive or negative energy balance.

For infants and children, a growth curve (physical growth curve) should be used when assessing inadequate or excessive energy intake. The course of growth should be observed longitudinally to ascertain whether body weight and height measurements follow the growth curve (physical growth curve), whether the body weight deviates greatly from the growth curve, without increases in the observed body weight, and whether there are any increases in the body weight that deviate greatly from the growth curve.

For the evaluation of nutrient intakes, the results of dietary assessment (estimated nutrients intakes) are to be used. This requires a full understanding of the significance and extent of the influence of measurement errors (particularly, under- and overreporting, and day-to-day variations) arising from the dietary assessment method used. It should be considered that day-to-day variations, in individuals, have a large effect on assessments.

The main application of EAR and RDA is in the prevention of the inadequacy of nutrients. When the EAR is not determined, the AI should be used instead. The probability of inadequacy can be estimated from the estimated intake, comparing the EAR and the RDA. When the intake is close to or above the RDA, it can be deemed that there is almost no risk of inadequacy. When the intake is above the EAR, but below the RDA, it is recommended to aim for the RDA. However, the intake is determined comprehensively taking into account factors

such as the intake status of other nutrients. Since the probability of inadequacy is 50% or more when the intake is less than the EAR, it is necessary to increase the intake. When using the AI, it can be deemed that there is almost no risk of inadequacy, if the intake is higher than the AI. However, the risk of inadequacy cannot be estimated even if the intake is less than the AI, as is evident from the definition of AI.

The UL is used when assessing the risk of the excessive intake of nutrients. When the estimated intake exceeds the UL, it is regarded as excessive intake.

The DG is used for evaluations related to the prevention of LRDs. Since some DGs are presented as a range, they should be compared with the estimated intake, taking into account the characteristics of each DG. Since LRDs develop as a result of a combination of factors, excessive emphasis should not be placed on one nutrient. It is recommended that a comprehensive assessment be performed, with an understanding of the importance of the nutrient in question, in relation to the LRD.

# • Planning and Implementing Dietary Improvements

An overview of dietary improvement planning and implementation, using the DRIs, on the basis of the results of dietary intake status assessments to improve the diet of individuals, is presented in Figure 7.



Figure 7. Planning and implementing dietary improvements, using the DRIs, to improve the diet of individuals

When planning and implementing dietary improvements, it is fundamental to use the results of dietary intake status assessments. Dietary improvements should be planned and implemented based on these evaluations. It is, therefore, important to sufficiently understand the characteristics of individuals. Such characteristics include sex, age, physical activity levels, living environments, and lifestyle habits. Clinical symptoms and clinical test data can be also

used, depending on the purpose.

BMI, or change in body weight, should be used to plan and implement dietary improvements in order to address energy intake inadequacy or excess. Diets should also be planned such that the BMI remains within the target range. When aiming for weight loss or gain, it is recommended to record body weight measurements roughly every 4 weeks, and to perform follow-ups for more than 16 weeks. For example, in a meta-analysis of 493 interventional studies conducted for weight loss, using dietary restrictions and/or exercise, the mean BMI was 33.2 kg/m<sup>2</sup>, the mean intervention period was 16 weeks, and the mean weight loss was 11 kg<sup>(24)</sup>.

The RDA should be used for nutrients for which the corresponding value is determined. When the nutrient intake is close to or exceeds the RDA, the current intake should be maintained; when the nutrient intake falls below the RDA, the intake should be increased so as to bring it closer to the RDA. However, intake should be determined comprehensively, taking into account feasibility, and the intake status of other nutrients. The AI should be used for the nutrients for which the corresponding value is determined. The current nutrient intake should be maintained if it is close to or exceeds the AI. However, the presence and risk of inadequacy cannot be estimated when the nutrient intake falls below the AI. When the nutrient intake is considerably lower than the AI, increasing the intake should be comprehensively considered, together with the intake of energy and other nutrients, anthropometric measurements, and clinical test results.

When the nutrient intake exceeds the UL, plans should be made to ensure that the intake drops below the UL. Nutrient intake that exceeds the UL should be avoided; if the intake exceeds the UL, proper diet should be promptly planned and implemented to resolve the problem.

When the intake of nutrients exceeds the DG range, an appropriate dietary plan must be formulated. However, it is recommended to elucidate the presence and degree of other nutritional factors and non-nutritional factors related to the LRD that is to be prevented and, comprehensively taking these into account, determine the degree of improvement in the intake of the nutrient in question. Moreover, considering the characteristics of the LRD, it is best to devise and implement a feasible, long-term dietary improvement plan.

When creating the above statements, the application examples of the previous Japanese DRIs were considered, based on the approach adopted by the *US–Canada Dietary Reference Intakes*<sup>(25–27)</sup>.

#### 4-4-2. Use of the DRIs to Improve the Diet of Groups

The basic concept behind the use of the DRIs to improve the diet of groups is presented in Figure 8.

Dietary intake status is assessed by applying the DRIs to estimate the proportion of individuals with possible inadequate or excessive intake, from the intake distribution of a

population. On the basis of the results, the DRIs may be used to propose appropriate energy and nutrient intake targets for the prevention of inadequate or excessive intakes and LRDs, leading to the planning and implementation of dietary improvements.

Furthermore, to achieve the target BMI and nutrient intake, the planning, implementation, and verification of public nutrition projects, such as the establishment of improvement targets for eating behavior/dietary habits and physical activity levels, and their monitoring, as well as the planning and implementation of various effective projects for improvement, can be conducted.



Figure 8. Basic concept for the use of the DRIs for improving the diet of groups

# • Assessing Dietary Intake Status

An overview of the assessment of dietary intake status, using the DRIs to improve the diet of populations, is presented in Figure 9.



Figure 9. Assessing dietary intake status, using the DRIs, to improve the diet of groups

# • Planning and Implementing Dietary Improvements

An overview of the planning and implementation of dietary improvements using the DRIs, on the basis of the results of dietary intake status assessments to improve the diet of populations is presented in Figure 10.



Figure 10. Planning and implementing dietary improvements using the DRIs to improve diet of

groups

BMI, or change in body weight, should be used to plan and implement dietary improvements for inadequate or excessive energy intake. Diets should be planned to increase the proportion of individuals whose BMI falls within the target range. Assessments should be performed at least twice, over several months (within at least 1 year), and this evaluation should use changes in body weight.

The EAR or AI should be used to plan and implement dietary improvements for avoiding the inadequate intake of nutrients. Diets should be planned to ensure that the proportion of individuals within a population, whose intake falls below the EAR, is as small as possible. If the median intake is close to or exceeds the AI, plans should be made to maintain this intake. When the median intake falls below the AI, it is impossible to determine if the intake is inadequate. Moreover, when the intake falls considerably below the AI, the need for the improvement of intake should be examined, on the basis of comprehensive judgment, taking into account factors such as the intake of energy and other nutrients, physical measurements, and clinical test results.

The UL should be used to plan and implement dietary improvements to avoid the excessive intake of nutrients. Plans should be formulated to ensure that the nutrient intake of all individuals within a population is lower than the UL. Intakes that exceed the UL should be avoided, and if the intake is found to exceed the UL in some individuals, action should be taken promptly to resolve the problem.

DGs should be used to plan and implement dietary improvements to prevent LRDs. Diets should be planned to increase the proportion of individuals whose intake is within or close to the target range. It is recommended to elucidate the presence and degree of other nutritional factors and non-nutritional factors related to the LRD to be prevented, and taking these comprehensively into consideration, the degree of improvement in the intake of the nutrient in question should be determined. Moreover, considering the characteristics of the LRD, it is best to devise and implement a feasible, long-term dietary improvement plan.

The above statements rely on the practical application of the examples in which the previous Japanese DRIs were considered, based on the approach adopted by the *US–Canada Dietary Reference Intakes*<sup>(25,26,28)</sup>.

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