Guide to Developing Accurate Nutrient Values

Health Canada
2007

Health Canada Santé Canada

TABLE OF CONTENTS

List of Tables

List of Figures

FORWARD

Nutrient information is used for a variety of purposes by many individuals. These users include consumers, food manufacturers and producers, academia, health professionals and government agencies. The nutrient values need to reflect the nutrient content of the food, and they need to be accurate as well as appropriate for their intended purpose.

In the past, nutrient values were generated in government and research laboratories and collated in food composition databases used by health professionals and researchers. With the new regulations on nutrition labelling, Nutrition Facts tables now allow consumers to compare the nutrient content of different products and to make informed choices at point of purchase. Ingredient suppliers must also provide nutrient information to their customers.

As a result of this, many more people including the food industry and private laboratories are now involved in generating and using nutrient data. Yet the specialization of food composition is a relatively new field. International standards, application to risk assessment studies and compliance testing of label values are all pressures demanding greater attention to data accuracy, information regarding variance, and documentation of data sources and quality.

Health Canada, in collaboration with the Canadian Food Inspection Agency, has prepared the *Guide to Developing Accurate Nutrient Values* to assist users in developing accurate nutrient values. It will help to understand some of the factors that cause nutrient values to vary in a food. As nutrient data are used for a variety of applications, this guide can help choose the appropriate approach or approaches for generating nutrient values that will be suitable for your intended purpose. However, this Guide is not designed to give you a precise step-by-step blueprint on how to develop nutrient values for your products.

To ensure its relevance, your feedback on the Guide is welcomed. Particular areas of interest are:

Does the document help you understand the process of developing nutrient values?
Does it address your specific needs?
Do you require clarification in any particular area?

Please send your comments to: nutrition_labelling@hc-sc.gc.ca

ACKNOWLEDGMENTS

This project could not have been completed without the tremendous effort and co-operation of many people. Health Canada would like to thank the Bureau of Nutritional Sciences and the Bureau of Biostatistics and Computer Applications, who guided the development of the technical content of the guide. Health Canada also appreciates the valuable assistance of officials from the Canadian Food Inspection Agency and Agriculture and Agri-Food Canada, who reviewed the manuscript and provided comments at various stages of development. Finally, sincere thanks are extended to numerous other experts, including the consultants who served as the lead writers for the project.

INTRODUCTION

Nutrient information is used for a variety of purposes by many individuals. These users include consumers, food manufacturers and producers, academia, health professionals and government agencies. The nutrient values need to reflect the nutrient content of the food, and they need to be accurate as well as appropriate for their intended purpose.

In the past, nutrient values were generated in government and research laboratories and collated in food composition databases used by health professionals and researchers. In recent years, consumers have become increasingly aware of relationships between the foods they eat and their health; they want to know more about the nutritional value of their food. This consumer awareness prompted, in part, the move toward voluntary and then mandatory nutrition labelling for prepackaged foods.

Nutrition Facts tables allow consumers to compare the nutrient content of different products and to make informed choices at point of purchase. Ingredient suppliers must also provide nutrient information to their customers.

As a result of this, many more people including the food industry and private laboratories are now involved in generating and using nutrient data. There is a wider range of people who need to collect nutrient information, along with expanded ways in which nutrient data are used.

> The intent of this document is to provide guidance to anyone who wants to develop accurate nutrient data.

Yet the specialization of food composition is a relatively new field. International standards, application to risk assessment studies and compliance testing of label values are all pressures demanding greater attention to data accuracy, information regarding variance, and documentation of data sources and quality.

So how can you generate nutrient values that are sufficiently accurate and representative for their intended uses? The most important factor to be considered is the inevitable variation of nutrient levels in the product. You need to know how much the nutrient levels vary and what conditions are associated with this variation.

This Guide describes the advantages and disadvantages of three approaches to generating nutrient values:

1. A direct approach: laboratory analysis of appropriately selected samples
2. An indirect approach: calculations based on nutrient data on specific ingredients (with or without laboratory validation)
3. An indirect approach: calculations based on generic values from reference databases

Generic values have a long history of use as sources of information for the nutrient content of foods. These data are particularly useful as sources of typical values for dietary intake assessment. In general, they tend to be the least reliable in the new context of needing product-specific information to meet the mandatory requirement to provide nutrient values on product labels. Laboratory analysis is a more reliable method for the development of product-specific information, but calculations based on ingredient data (especially when validated by periodic laboratory analysis) can produce accurate results in certain instances at less cost. You may want to use different approaches for different nutrients in the same product.

Nutrition Facts tables are a special case of nutrition labelling. Development of nutrient values for Nutrition Facts tables responds to new standards and expectations in the area of nutrient information. It is the manufacturer's responsibility to ensure that the values are accurate and reflect the product, within the guidelines set out by the Canadian Food Inspection Agency (CFIA). It is up to you to determine the degree of precision needed for each of your products and to take appropriate measures. Having a good understanding of your process, your product and the associated variability will allow you to determine the best approach at the least cost.

The intended use of the data will determine the appropriate treatment of the data.

You should document thoroughly all procedures and results of the approach or approaches followed. Systematically organized information, preferably in electronic format, will contribute to the efficiency of your food composition program and will be an invaluable asset in the event that a value is questioned.

Purpose of this Document

This document will assist you in developing accurate nutrient values. It will help you to understand some of the factors that cause nutrient values to vary in a food. As nutrient data are used for a variety of applications, this guide can help you to choose the appropriate approach or approaches for generating nutrient values that will be suitable for your intended purpose.

This Guide is not designed to give you a precise step-by-step blueprint on how to develop nutrient values for your products. Rather, it is designed as a guide to inform you of the key factors that have an impact on those values. It does not recommend or advocate any particular approach for your specific product, as you are in the best position to understand your product, processes and the degree of certainty or precision needed.

This document is divided into two sections:

- **Part 1** presents the key steps involved as well as some of the options and factors to consider when developing a program to generate nutrient values. It will help users of those values, including decision makers and senior managers in the food industry, to understand the process.

- **Part 2** provides further details on the key steps. It includes a discussion of the many uses of nutrient data, the characteristics of nutrient values and the importance of variation in determining nutrient values. It also describes the main features, advantages and disadvantages, and implications of several different approaches to determining nutrient values. It includes a separate section on the issues pertinent to nutrition labelling.

This document has a strong focus on many of the issues faced by manufacturers as they develop accurate nutrient values for the labelling of their products. Yet many of the principles apply to the collection and analysis of products and nutrients for a wide variety of applications.

The calculations from the data, however, are often different for different uses. For example, nutrient values included in Nutrition Facts tables will be rounded according to specific criteria, whereas values provided by suppliers should be unrounded values.

A note on terminology…
In this document the term "manufacturer" in most instances refers collectively to producers, manufacturers, processors, importers, distributors and suppliers of food products and ingredients.

Part 1: Getting Started

Part 1 is designed as an overview for senior managers and other decision makers. It outlines the process needed to obtain accurate nutrient information. It sets out the important information, considerations and decisions that you will need to make as you go through this process.

Eight steps are involved in developing accurate nutrient values:

- Determine how you intend to use the nutrient values.
- Gather the information available about your product.
- Consider your options.
- Assess your options.
- Identify gaps and plan how to fill them.
- Choose an approach.
- Apply the approach and calculate the results.
- Document your approach.

Part 1 focuses on providing you with an outline of these steps. A glossary of terms and acronyms can be found in **Appendix A**.

I. Determine How You Intend to Use the Nutrient Values

The first step in developing accurate nutrient values is to determine how you plan to use the information. Are you compiling the data for a research project, gathering industry data for a specific commodity, planning to include the data in a reference database such as the Canadian Nutrient File (CNF),[1] reformulating a product to meet specific nutrient requirements, or developing a Nutrition Facts table specific to a particular product?

You may be gathering data for more than one application; for example you may want to include the information in a reference database as well as to use it for nutrition labelling.

It is also important to recognize that depending on your use or application, the nutrients may be defined differently. Details on this can be found in **Appendix B**.

Once you know how you intend to use the nutrient values, you can determine which nutrients you need to measure. For example:

- If you are trying to reformulate a product to reduce its *trans* fat content, you will probably want to look at the entire fatty acid profile.
- If you are developing a Nutrition Facts table for your product you will need to determine the values for energy and the 13 core nutrients.
- If you want to make a health claim related to a nutrient that is not mandatory in the Nutrition Facts table (e.g. omega 3), you may need to determine the values of additional nutrients.
- If you are conducting a study on the nutrient values of a raw, single-ingredient food for inclusion in a reference database, you will likely require additional nutrients that are of interest for health and nutrition (e.g. Vitamin B_{12} in meat products).

Knowing how you intend to use the nutrient values, you will also be able to determine which approaches are the most suitable.

[1] CNF: www.healthcanada.ca/cnf

II. Gather the Information Available About Your Product

A. What Basic Information Do You Need?

You need to assemble key information that may affect the nutrient content of your product. The following chart provides some examples of basic information you need.

Examples of Basic Information to Gather About Your Product	
Raw, single-ingredient foods	**Formulated foods**
• varieties, race, breed or species and perhaps trim level • production conditions (locations, relative volumes, how the lots are determined, soil type, use of fertilizer, composition of animal feed)	• ingredient suppliers • nutrient values for each of your ingredients • product formulas • processing conditions (locations, relative volumes, how the lots are determined)

B. What Other Information Can Help You?

Here are some examples of other information that will assist you:

- Can you group your products according to common characteristics and conditions of processing, such as cuts, varieties, formulations or recipes?

  This will help you decide how to sample your products and determine which approach is the most appropriate. For raw, single-ingredient foods, look for similarities and differences (e.g. trim level). Check formulations to find products for which most ingredients are the same and in similar amounts (e.g. products that are similar and only have different flavours).

  For example:

  - A bakery may use the same dough formulation to make a number of differently shaped rolls such as hamburger buns and hot dog buns.
  - A confectionery manufacturer may make candies that differ only in a flavoring ingredient.
  - A pork producer may sell a variety of cuts from the same muscle group.

- How homogeneous or consistent is the product?

  Is it reasonable to expect one set of nutrient values to represent all of the product produced? Examples of products that might be homogeneous include:

  - one variety of carrots grown under similar conditions
  - cuts of meat from the same muscle
  - items identified under one label of a processed product in which the ingredients are the same and the process is constant

  Examples of products that may need to have separate sets of nutrient values include:

  - special varieties of tomatoes grown under different conditions that would change the vitamin content
  - processed products for which an ingredient supplied by two different suppliers is significantly different

- What are the key ingredients in your product? What are the key nutrients in those ingredients and their approximate levels?

  Substituting a key ingredient, such as an oil, may change the nutrient profile of your product.

  Which of the nutrients that are mandatory for nutrition labelling are present?

  Does the product contain other nutrients of significant health concern?

- Are any of the nutrients highly variable?

  If yes, you probably will want to explore this in more detail, as it may have a large effect on determining the nutrient levels of your product.

- Which nutrient levels are affected by processing (e.g. during cooking, baking, dehydrating)?

  Can you quantify these changes from previous studies or from the literature?

C. How Do You Determine a Point of Reference?

It is useful to establish the approximate level of each nutrient in your product, to give you a point of reference. This will allow you to determine whether the nutrient is present in a significant quantity or perhaps not at all in your product; whether the use of generic values is appropriate; and (later) whether values determined either by laboratory analysis or by calculation from database values are reasonable.

You can determine a point of reference by:

- examining historical information on your own product
- referring to the scientific literature
- locating generic values in reference databases such as the CNF
- surveying similar products in the marketplace
- estimating nutrients in the product from ingredient information provided by suppliers, and accounting for the effects of processing if necessary
- conducting a small study (*pilot*)

III. Consider Your Options

Two general approaches can be used for generating nutrient values. They differ in the manner in which nutrient data are obtained:

- **Direct approach:** you measure the nutrient levels in the food or ingredient of interest directly, by product sampling and laboratory analysis (**Section A** on the next page).
- **Indirect approach:** you determine the nutrient values indirectly, by using information obtained from other sources.

  Data sources can include:

  - Ingredient-specific information from suppliers and from your own records (**Section B-1**, page 13)
  - Non-specific information from competitors' products, or generic information from literature or published databases (**Section B-2,** page 16)

Both approaches follow the same basic steps:

- Gathering the information on the product, its nutrients and the nutrient levels
- Assessing the information
- Using the information to calculate the nutrient values for the intended use

How do you choose which approach or approaches to use? You need to consider a variety of information:

- The key nutrients in your product
- Intended uses of the information (see also **Part 2, Chapter I**, page 27)
- The sources of variation in your product (see also **Part 2, Chapter II**, page 30)
- Advantages and disadvantages of the different approaches

Not all approaches are equally suited for all uses or for all products. The approaches will differ in:

- specificity of the data provided with respect to your generic product
- flexibility in being able to treat the data arithmetically in different ways for different uses
- degree of input by the producer or manufacturer into generation of the data or calculation of the final results
- how well they capture the variability in products
- resources required

Different approaches may be suitable for different nutrients in the same product, so you may choose to use a combination of approaches.

A summary of the major approaches with their particular strengths and weaknesses is provided in this section. Further details on each approach can be found in **Part 2, Chapter III** (page 39) and **Chapter IV** (page 54).

You may want to hire a consultant to assist you in determining which approach is suitable for your products, as well as in implementing the approach. Some key considerations in choosing a consultant can be found in **Appendix C**.

A. Direct Approach: Product Sampling and Laboratory Analysis

The direct approach uses laboratory analysis of the end product to determine nutrient values. The nature of the end product can range from a raw, single-ingredient food to a complex processed food made from many ingredients.

Three basic steps are involved in the data collection phase, regardless of the product:

- Selecting a suitable sample of food units from the entire product line
- Possible *pooling* or *compositing* of units
- Laboratory analysis for the nutrients of interest

Once the data have been collected, the nutrient values need to be assessed and then calculations made for your particular use. Details of the steps involved can be found in **Part 2, Chapter III** (page 39).

The direct approach has advantages and disadvantages depending on your application. These are outlined in Table 1 on the next page.

Table 1:
Assessment of the Direct Approach: Product Sampling and Laboratory Analysis

Advantages	Disadvantages
• Laboratory analysis is usually performed on finished products. This makes it very product-specific, and the results will reflect any effects of processing. • Appropriate sample design can account for major sources of variation and allow the development of values that reflect the whole product line. • The nutrient values reflect the current product with current ingredients and processes used. For nutrients that vary widely in one or more of the ingredients or that are known to respond inconsistently to processing, laboratory analysis of appropriate samples is more likely to yield current, relevant values than calculations based on ingredient information. • Analyzing a number of samples will allow you to quantify and characterize the variability of the nutrient content in the product. This information is needed to assess the precision of the resulting nutrient values. • The unrounded values will be available. This will provide flexibility in combining and calculating the data in different ways for different uses. • You have control over how and where the units are collected that will be used in the development of the nutrient values. This gives you a better understanding of how well the sample represents your product, and greater confidence in the resulting nutrient values.	• Laboratory analysis can be more costly and less convenient than an indirect method if you do not have the expertise and equipment in-house. In that situation you would need to contract out the analysis to an accredited laboratory. • Specialized expertise can be required to plan the sampling, conduct the laboratory analysis and perform the calculations appropriately. • The sampling plan has to be carefully determined. Otherwise key sources of variation may not be accounted for appropriately, and the results may not be representative of your product. The services of a consultant with expertise in this area may be helpful. (Details on choosing a consultant are found in **Appendix C**.) • You must take care in choosing a laboratory with the required expertise to perform the analysis. (Details on choosing a laboratory can be found in **Appendix D**.) • Specialized expertise may be needed to review and evaluate the laboratory results. (Details on reviewing the results of laboratory analysis can be found in **Appendix G**.)

Appropriate uses of laboratory analysis

Laboratory analysis is useful for:

- testing end products for nutrition labelling purposes
- generating ingredient data to be provided by suppliers where there will be secondary use of the data
- generating values for processed foods when nutrient values of one or more significant ingredients are missing, uncertain or highly variable; when the effect of processing on the nutrient content is unknown or inconsistent; or to ensure that criteria for claims are met
- validating indirect measurements

B. Indirect Approaches

1. Calculation from ingredient-specific information

For indirect approaches, you collect nutrient information, or data, for each ingredient from your suppliers. Then you calculate the nutrient content in the final product from these data based on the formulation or recipe. You may need to make adjustments to the nutrient values to account for changes that occur during processing, transportation and storage.

Ingredient-specific information can be obtained from your suppliers or sometimes from brand name data in a commercial or company database. You need to assess this ingredient information to ensure that it is representative of the ingredients or products you are using. It is generally preferable to use the nutrient information from your ingredient suppliers as this is most likely to represent the ingredient you are using.

Manufacturers can assemble databases of ingredient-specific values from the information provided by their suppliers. Often these databases are used to calculate interim values for products under development. In some circumstances, the databases are suitable for deriving values for nutrition labelling.

For certain products, you can fine-tune your ingredient database over time by validating the values through laboratory analysis, and by applying a software program that can account for nutrient changes during processing and storage to calculate accurate nutrient values.

This indirect approach has advantages and disadvantages depending on your application. These are outlined in Table 2 on the next page.

Table 2:
Assessment of the Indirect Approach: Using Ingredient-Specific Information

Advantages	Disadvantages
• Values generated by calculation from ingredient-specific information can be specific to your product formulation. • This approach can be less costly and more convenient than laboratory analysis when it can be done with appropriate software and individuals who have the required expertise.	• The value of this approach is dependent on the quality of the ingredient information. It requires accurate and representative information on supplier-specific ingredients used in the product formulation. • Data on all of the desired nutrients may not be provided by the ingredient supplier. There is currently no regulatory requirement for suppliers to provide information beyond that on core nutrients, unless the ingredient contains added vitamins or minerals. • If your supplier has used outdated or unreliable information from a database, it may affect the reliability of the data for the final product. • It is difficult to assess whether the information is sufficiently precise. The source of the ingredient data and the nature of the variation reflected in the data may not be known. • You have little or no control over the manner in which the data were obtained (e.g. sampling, laboratory used, analytical approaches) or manipulated, and over the final presentation, adding uncertainty to your results. Certificates of laboratory analysis can be requested from suppliers to minimize some of the uncertainty. • Rounded values may be provided, which limits the precision of further calculations. • It may be difficult to account accurately for the effects of processing. Published retention factors are not comprehensive and do not take into account all changes due to industrial processing methods such as interactions among heat, acidity and moisture within and between ingredients. (Additional information on retention factors and accounting for processing effects can be found in **Appendix E**.) • Periodic validation using laboratory analysis is required to ensure that the data generated using ingredient-specific information are accurate and representative.

Appropriate uses of the indirect approach
- using ingredient-specific information

Using ingredient-specific information is suitable for:

- individual counselling, where access to combinations of generic data and brand name data can be used to assess the diet, calculate recipes or plan menus
- the initial stages of product development, to estimate nutrient values and assess the ability to use potential claims
- nutrition labelling, if you have good information on your ingredients and can account for the effects of processing

2. Derivation from non-specific product information

The second indirect approach also uses established data. However, unlike the first indirect approach, in this case the information is not specific to the ingredient or perhaps to the product itself.

For this approach, you may obtain data from reference databases such as the CNF[2] or the US Department of Agriculture's National Nutrient Database for Standard Reference (USDA-SR),[3] from competitors' products or from the literature.

- Generic values found in reference databases most often have been derived by combining brands of similar products (e.g. all major brands of ketchup, various varieties of oranges or similar beef cuts from various producers).
- These data also may be developed by a commodity association based on data from different producers, resulting in a single value for a hypothetical, generic product.
- For some products that have been standardized in Canadian food regulations, such as sugar and butter, the profiles are defined, making the single value a good representation of all units.

Government reference databases generally follow established international standards for data quality and are accompanied by documentation outlining the source and type of data.

As with the other approaches described, this indirect approach has advantages and disadvantages depending on your application. These are outlined in Table 3 on the next page.

[2] CNF: www.healthcanada.ca/cnf

[3] USDA-SR: www.nal.usda.gov/fnic/foodcomp/Data/SR17/sr17.html

Table 3:
Assessment of the Indirect Approach: Using Non-Specific Product Information

Advantages	Disadvantages
• This approach is less expensive than laboratory analysis and data may be readily available for some nutrients and some products. • Using a reference database may be cost-effective in the initial stages of product development to approximate levels of nutrients in the product. • You may be able to use a reference database to find standard average nutrient values for products for which you have only a generic description of the product (e.g. "tomato soup"), as in a dietary assessment. • Because generic databases such as the CNF are updated at regular intervals, they can serve as a standard reference. You can track trends over time by comparing the results of a similar study conducted using data from two different time periods. You also can compare different research studies that were conducted using the same database with the same date of issue.	• Generic databases may not include data on all of the nutrients you want. (Further information on nutrient data gaps in some common reference databases can be found in **Appendix F**.) • Sometimes even when the nutrient names in a generic database appear identical to the nutrients you are looking for, they can in fact have different meanings or different units of measurement. • You cannot determine how well nutrient values from a generic product match your specific product where the ingredients, formulation or manufacturing processes may be different. In addition, these values may not consider all losses due to storage. • Further calculations accumulate the uncertainty and imprecision of each value used in the calculation and may affect the usefulness of the final results. • While some estimate of variability, such as *standard error*, may be available in the database, it is usually of limited use in further calculations for a number of reasons (e.g. additional information about the construction of the estimate that is needed to use it appropriately is not usually provided; the calculation does not relate to a specific product or ingredient). • It may be difficult to account accurately for the effects of processing. Published retention factors are not comprehensive and do not take into account all changes due to industrial processing methods such as interactions among heat, acidity and moisture within and between ingredients. (Additional information on retention factors and accounting for processing effects can be found in **Appendix E**.) • In many cases, it is difficult to determine when and how the data were collected and to ensure the data are current. • There may be variability based on the age of the data or the country of origin. For example: o Changes in regulations may have changed nutrient levels (e.g. data for flour in Canada have changed in the last 10 years with requirements for fortification with folate). o Beef and pork cuts are leaner than they were 20 years ago. o American beef may have a different nutrient profile than Canadian beef does.

Appropriate uses of the indirect approach
- using non-specific product information

Using non-specific product information is particularly suited for:

- diet assessments
- recipe development
- menu planning in which ingredients or menu items are not specific
- population nutrition surveillance activities in which nutrient intake distributions are used to conduct risk assessments (such as modeling for fortification purposes)

This approach also is useful in the initial stages of product development to evaluate whether nutritional targets can be met.

Use of generic information from a reference database for calculating nutrient values for labelling purposes generally is not recommended; you cannot assess the degree to which the generic information matches your product formulation or specific ingredients and processes.

IV. Assess Your Options

Once you have an understanding of your options, it is important to assess those options based on your available resources and on the degree of precision and accuracy you need for the intended purpose.

A. What Resources Are Available?

Some of the resource considerations include the availability of in-house expertise and of funds, the time frame for the project, and the nutrient information that is available.

1. Expertise

Determining the nutrient levels for your product requires expertise in several areas, including sample design, laboratory analysis, arithmetic treatment of the data, and database manipulation, as well as an understanding of the effects of processing.

In addition, if you are preparing Nutrition Facts tables, you need an understanding of the Food and Drug Regulations,[4] including the prescribed rounding rules, as well as the CFIA *Nutrition Labelling Compliance Test*.[5]

This Guide explains the steps required and gives an overview of the issues, but does not provide all of the details that may be required. If you do not have access to this type of expertise in-house, you may want to hire consultants to assist you. (Some information on hiring a consultant is provided in **Appendix C**.) You may be able to get help identifying suitable consultants or statisticians, or databases that may be applicable to your sector, by contacting a marketing board, professional association or industry association.

2. Budget

The cost of each approach differs. You need to examine all of the suitable approaches and determine which is best for your application given the financial resources available and the precision or certainty you need. Some choices will affect the quality and suitability of the data for its intended use.

Additional information or funding may be available from various initiatives by commodity associations or industry associations.

---

[4] Food and Drug Regulations, Sections B.01.401 and B.01.402
www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_b-text-1.pdf

See also Health Canada's nutrition labelling Web site:
www.healthcanada.ca/nutritionlabelling

[5] CFIA *Nutrition Labelling Compliance Test*: www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

3. Time frame

Some approaches by their nature will take longer to execute. You need to plan your process so that you can collect data to properly account for variation in your product. To do this, you may need to sample over several seasons, several lots and several plant locations. If you need to publish the data, you also should allow time for layout, checking proofs, and printing.

4. Available nutrient information

As detailed in **Section B** below, you must collect all of the information available about your product and your process. You need to plan ahead because if you find that you are starting with little information, having to obtain that information will have an impact on time and cost.

B. How Much Precision and Accuracy Do You Need?

Depending on how you plan to use the nutrient values, very different consequences can arise from the amount of uncertainty in the values and the extent to which the values are representative of your specific product. You need to consider what impacts are acceptable for your intended use.

For example, if your values will be representing a generic product and you will be using a mean value, you may not need as precise a value as if you were producing values for nutrition labelling. In the case of a Nutrition Facts table, there are specific tolerances and expected performance criteria, defined in the CFIA *Nutrition Labelling Compliance Test*,[6] that will have to be taken into account in your decision making. (Further information on nutrition labelling requirements is outlined in **Part 2, Chapter V, Section B**, page 64).

When developing nutrient values for any application, you need to balance the costs with many factors, including:

- the risk that a value may be found to be out of compliance with the Food and Drug Regulations
- consumer expectations for representative values

[6] CFIA *Nutrition Labelling Compliance Test*: www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

V. Identify Gaps and Plan How to Fill Them

If you still have questions or gaps in your information, you may wish to examine administrative records, to contact your suppliers, to conduct a pilot study, opr to hire someone to help assess and fill the gaps.

VI. Choose an Approach

Each product is unique. With an understanding of your product and process, you are in the best position to identify which factors may cause the nutrient values to vary and by how much, and to choose which approach is best.

It may be to you advantage to use a combination of approaches. You are not limited to using one approach for all of your products, or even for all of the nutrients in a single product. You need to examine your product line, the factors affecting variation and the intended use of the data to determine if a combination of direct sampling and indirect calculation using a database is suitable. You may choose to conduct a laboratory analysis on a group of nutrients and to use values calculated from ingredient information where little variation is expected.

When you examine your products and/or formulations (recipes), you may find that most of the ingredients are the same and present in similar amounts, (e.g. similar products which have different flavours). In that case, you may be able to choose a representative product to have analyzed, compare the laboratory values with those generated by a database and then use the database software to calculate the nutrient values for similar products.

You can use a reference database to see which nutrients your product is expected to contain. If you product is known not to contain vitamins, for example, you probably would not need to have a laboratory analysis done for those nutrients.

Examples of Using a Combination of Approaches	
Description	**Example**
Analyzing one product by laboratory methods and then using a validated ingredient database to compare the other products in the group with that analyzed product	In a series of pastry products, which may differ only in the filling, you may choose to analyze one product, enter the nutrient values in a database, and compare the values obtained with those from laboratory analysis. If the values for the nutrients are close, you may decide to do the remaining products by database calculation.
Conducting laboratory analysis for the most significant nutrients in your product and using literature values or a generic database value for the others	As pork is an important source of thiamin, you will likely want to analyze for thiamin if you are generating data on pork cuts for a reference database. Conversely, literature values might suffice for Vitamin C as pork is not a major contributor of that vitamin.
Conducting laboratory analysis on the nutrients in your product that have the greatest variation	In a fried product, for which you may change the supplier of the oil, you may wish to analyze for *trans* fat as it is highly variable.
Analyzing only for the nutrients that you know are present	In raw meat, where there is no fibre, you would not analyze for that particular nutrient, or you may use a reference database value.
Conducting laboratory analysis to increase the certainty of the nutrient values for a nutrient that is the subject of a nutrition or health claim	If you have reformulated a product to be "reduced in fat", you may want to analyze both formulations to ensure that the product to carry the claim contains at least 25% less fat per reference amount of the food than the reference amount of the original product.

VII. Apply the Approach and Calculate the Results

Once you know which approach or approaches you plan to use, you are ready to apply the approach and calculate the nutrient values. An outline of the steps involved is presented here. Details on each approach and the treatment of data specific to that approach, including tools that will help, can be found in **Part 2, Chapter III** (page 39) and **Chapter IV** (page 54). Preparation of nutrient values for nutrition labelling is a special case; details can be found in **Part 2, Chapter V** (page 64).

Each approach follows the same three steps:

A. Gather the Data

- Assemble everything you need to determine the nutrient values you require.
- In the direct method this will include collecting product samples for analysis.
- In the indirect methods, it may include gathering supplier data, commodity association data or literature values.

B. Assess the Information

Next, review the information that you have.

- If using sampling and laboratory analysis, confirm that the unrounded results are reported in the serving sizes and nutrients units that you need for every sample analyzed; that the methods are documented; and that you understand how *outliers* (values that are unusually large or small) and values that are below the limits of detection are treated. More information on reviewing the results of laboratory analysis is available in **Appendix G**.
- If using an indirect approach, ensure that the serving sizes or units are correct; the data used match your product; the information is current; the sources of the information are known; the values are presented in an unrounded format; and the effects of processing are taken into account. Also verify whether averages are used.

C. Calculate the Nutrient Values

You need to keep in mind the intended use when calculating the nutrient values. Different uses require different treatment.

- In the laboratory approach, the raw data allow greater flexibility in the types of calculations that can be performed. The same data can be treated differently to address different uses.
- If you are combining ingredient data, software is available that can assist you in the calculations. However, you need to adjust for the effects of processing and be aware of the limitations if rounded values are used. (Critical considerations in choosing software can be found in **Appendix H**.) You can encounter errors in the calculations

if the correct units or serving sizes are not used. As the variation of nutrient content is unknown, it is difficult to know how to integrate it in the treatment of the data.

> You can encounter errors in the calculations if the **units** in which the nutrients are expressed or the **serving sizes** of the ingredients are not the same as those within the recipe or formulation.

VIII. Document Your Approach

It is essential that you document all of your process steps to ensure that you can repeat the procedure and demonstrate how your values were obtained.

- In laboratory analysis, some of the key items to document are how the sample units were collected and combined; methods of analysis; the date the analyses were done; and who conducted the analyses.
- In any indirect method, it is important to record the sources of your information; how the effects of processing were taken into account; and whether laboratory analysis was used to validate the results.

PART 2: THE DETAILS

Details on each approach to determining nutrient values described in **Part 1** are presented in the following chapters. Each approach follows the same process of:

- Gathering information
- Assessing the information that you have gathered
- Calculating the nutrient values for the intended use

Chapter V provides further information on issues specific to the preparation of nutrient values for Nutrition Facts tables.

I. Uses of Nutrient Data

Nutrient data are used for a variety of applications, which include:

- Nutrition labelling
- Nutrition surveys
- Research and product innovation
- Food intake assessment and diet counselling
- Recipe analysis
- Nutrition education and information

A. Nutrition Labelling

Nutrition labelling is an application that has recently received much attention with the adoption of regulations for mandatory nutrition labelling in Canada.[7] The food industry also uses nutrient information to determine if a food meets the conditions specified to carry a nutrient content claim, a health claim or a comparative claim. More information on nutrition labelling and Nutrition Facts tables can be found in **Part 2, Chapter V** (page 64).

B. Nutrition Surveys

Many stakeholders, such as federal and provincial governments, hospitals, universities and research organizations, use nutrient data to support population nutrition surveillance activities. This can be used to track trends in eating behaviour and in dietary patterns, and can allow inferences to be made between eating behaviour/nutrient intake and health/disease. It can also provide information to be used by Health Canada and other agencies to conduct risk assessments, which then can be used to develop health policies.

C. Research and Product Innovation

Industry and government use nutrient data to support research activities such as formulating products to meet specific nutrient criteria. Others study nutrient interactions such as the effect of phytate on mineral absorption, while some need baseline information on the top food sources of specific nutrients. Some individuals use nutrient data to ensure foreign regulations are met or to market products in foreign countries.

[7] The Food and Drug Regulations, Part B. The regulations for nutrition labelling begin in Section B.01.401. www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_b-text-1.pdf

See also Health Canada's nutrition labelling Web site: www.healthcanada.ca/nutritionlabelling

D. Food Intake Assessment and Diet Counselling

Dietitians conduct assessments of nutrient intake on individual clients, such as those who have cardiovascular diseases or any other type of disease with a special dietary need. This helps them determine targets in their diet counselling programs.

Some consumers use nutrient data to assess their own diets or those of their families and to learn how to make healthier food choices. Consumers may also use the data to determine where they can make substitutions to add variety to their diet while maintaining similar nutrient intakes.

E. Recipe Analysis and Menu Planning

Recipe publishers and food writers use nutrient information on basic foods to create profiles for recipes in cookbooks, magazines and newspapers. Health professionals create menus with specific nutrient targets for institutional feeding of groups, such as in day cares and hospitals.

F. Nutrition Education and Information

Health professionals and communicators use nutrient data to develop teaching tools and other resources to enable consumers to make healthy food choices. Consumers themselves are also making growing demands for access to more nutrient information at point of purchase. Consumers also often consult reference databases such as the Canadian Nutrient File (CNF)[8] or the US Department of Agriculture's National Nutrient Database for Standard Reference (USDA-SR)[9], available on the Internet or through various publications such as *Nutrient Values of Some Common Foods.*[10]

[8] CNF: www.healthcanada.ca/cnf

[9] USDA-SR: www.nal.usda.gov/fnic/foodcomp/Data/SR17/sr17.html

[10] *Nutrient Value of Some Common Foods*: www.hc-sc.gc.ca/food-aliment/ns-sc/nr-rn/surveillance/e_nutrient_value_of_some_common_.html

All of these applications require accurate nutrient data. However, each has its own requirements and characteristics, which may differ from the others.

- Some applications require very specific information. For example, a manufacturer requires product-specific values for a product label.
- Other applications require generic data that represent the bulk of "like" (similar) products sold in the marketplace. For example, generic data may be suitable for surveys and risk assessments.

To determine the requirements for your data, you need to understand the intended use of the data and the impact that nutrient variability will have on its intended use. How your data will be treated will depend on who will be using the data and for what purpose.

Chapter III (page 39) explores the importance of variation in determining the nutrient content of your food.

II. Characteristics of Nutrient Data

No two units of the same product are identical. A value for a particular nutrient in a food or ingredient is a single representation of the level of that nutrient in many separate units of the same food or ingredient. In reality, the true nutrient value inevitably will be different from unit to unit, even for products grown side by side, or produced one after the other. In some cases the difference may be small, and in other cases it may be large. The nature of the range in values, or spread, is termed *variation* or *variability*.

Sometimes nutrient values are meant to represent a single ingredient or food from a specific supplier or brand. In other cases, values are meant to represent a much larger collection of the food or ingredient spanning a number of suppliers, brands, or even slightly different recipes; the nutrient content of the specific products that are to be represented may differ widely from one another and from the generic nutrient value reported.

Depending on your needs and intended uses, the variability plays a different role when choosing a method to develop the nutrient values. Before considering what approach is suitable for developing nutrient values for your use, you need to understand what makes products differ and how that affects the nutrient values.

For example:

- Amounts of Vitamin A and fat in frozen lasagna will vary between production lots, and there will also be differences between trays drawn from the same lot. These differences result from such things as variation in the nutrient content of the ingredients and variability in amounts of ingredients used and in processing factors.
- Similarly, differences in the Vitamin C content of fresh tomatoes will result from natural variation between varieties, enrichment of soils, and losses that may occur during transportation and storage.

A. Factors that Affect the Nutrients in Your Products

The factors that cause the nutrient content of a food to vary are unique to the product (the variety, breed or species); the conditions of production of a raw, single-ingredient food; and the formulation and the manufacturing processes of a processed food.

You are in the best position to identify these factors, and then determine which ones have only a small effect and which ones have a large effect and should be considered.

Accounting for the range of nutrient variation occurring in a food is the foundation of developing representative nutrient values. Whatever approach (or approaches) you eventually choose for generating nutrient values, accounting appropriately for nutrient variation increases the probability that the nutrient values will reflect most of the food product line, within chosen tolerance limits.

Some of the factors that influence the nature of the nutrient variation include:

- natural variation in nutrients
- manufacturing and processing influences
- transportation and storage influences

You want to be as confident as possible that the key sources of variability of the nutrients in question are considered as you plan how best to determine nutrient values for your specific use.

1. Natural variation in nutrients

Natural variation occurs in raw, single-ingredient foods as well as ingredients used in products that are processed further.

The nutrients in a raw, single-ingredient food may vary from one variety to another; from one geographical location to another; from one season to another; and from one muscle cut to another. They also may depend on factors such as the soil or feed used. Table 4 illustrates some factors that contribute to natural variation in nutrient content.

This variation is also clearly of importance to manufacturers who use these products as an ingredient in their process. Each shipment of an ingredient from a particular supplier may differ somewhat from the ones before it, because its ingredients, origin and/or the conditions under which they have been produced, stored and transported are not identical. Adherence to properly drafted ingredient specifications can minimize variations in nutrient levels, but some differences are inevitable.

Table 4: Sources of Natural Variation in Nutrient Content

Sources of Natural Variation	Examples
Foods of Plant Origin	
Ingredients derived from different varieties of the same plant	• Flours milled from hard wheat are higher in protein and lower in carbohydrate than those from soft wheat.
Soil type and fertilization	• Selenium content of grains is directly affected by the soil level of this mineral, either naturally occurring or supplied by fertilizer.
Changes in nutrient concentration or proportion due to maturing of the plant	• Green soybeans are approximately 32% solids; mature soybeans about 91%. • Naturally occurring enzymes in fresh vegetables and fruit degrade vitamins over time.
Season and light exposure	• Red tomatoes field-grown in summer typically contain at least twice as much Vitamin C as those grown in greenhouses in other seasons.
Foods of Animal Origin	
Breed of animal	• Different breeds of cattle will vary in their fat content.
Age of animal	• Beef typically contains about twice as much iron as veal.
Season	• The fat content of herring varies widely over the year.
Composition of feed	• Adding flaxseed oil to the diet of hens alters the fatty acid profile of their eggs. • Cows fed primarily on pasture in the summer produce butterfat higher in Vitamin A than in the winter.

2. Influences of manufacturing and processing

The following chart outlines some common sources of variation related to manufacturing and processing. Asking questions like these will help you understand the variability in your product.

Understanding the Variation in Your Product

• How many manufacturing or production locations do you have?
• Does each location use exactly the same formulation?
• Do they use the same equipment?
• Do they use the same ingredients and suppliers?
• Do batch sizes vary?
• Are all of the operators experienced?
• Do you have good process control?
• How many shifts are there in each location?
• Do you use more than one supplier or source for an ingredient?
• Do you substitute one ingredient for another?
• Are there variations in the ingredients:
  o due to season?
  o due to geographic location?
  o due to differing storage practices?

Even if you have a formulation that does not vary—using ingredients from a single source and good process control—differences in nutrient values may be observed between batches. For example, there could be differences between large batches compared with small batches, a batch from the beginning of a shift compared with one from the end, batches produced at the same plant by different shifts, and batches produced at different plants.

During manufacturing of ingredients or food products, nutrients may be altered or destroyed in reactions involving heat, light, oxygen, enzymes, microorganisms and other food components. You can minimize the nutrient variation attributable to these influences by consistently adhering to standardized ingredient storage, and manufacturing and packaging procedures.

3. Influences of transportation and storage

The nutrients in many foods are subject to changes during transportation and storage. Nutrients levels can change as foods age and as a result of changes in temperature, light conditions, humidity and exposure to air.
The influences of transportation and storage depend on the food and the nutrient. Some nutrients and some foods are very sensitive to changes, whereas others are not. For example, Vitamin C can be lost easily as an orange matures, and the proportion of starch to sugar in a potato changes during storage, whereas the amount of protein in a steak is relatively stable.

Under less-than-ideal storage and transportation conditions, changes can proceed at an accelerated rate, with resulting deterioration of product quality and nutrient content. Proper packaging and attention to proper storage conditions can minimize the changes. However, even in properly packaged and stored foods, changes in nutrient composition can still occur at low levels.

Transportation and storage conditions have an influence on the nutrient value of foods and ingredients. You need to understand if they are important factors in determining the nutrient values of your food product.

> Accounting for nutrient variability is the foundation of determining accurate, representative nutrient values.
>
> No matter how well you execute the other steps in determining nutrient values, if you do not properly account for variation, regardless of the sources, you will be much less likely to end up with accurate nutrient values.

B. Quantifying the Characteristics of Nutrient Values in Foods

Two of the most common ways to quantify the characteristics of nutrient values in your product are those that provide some measure of:

- a typical value (such as average/mean or median)
- the spread of the data away from this typical value (such as variance, standard deviation, standard error of the mean) – quantifying the size of the differences discussed in **Section A** above

A third term that is sometimes reported with nutrient values is *standard error of the mean.*

1. Measures of typical values

Average

Average is a term that is generally understood as a measure of a typical value for a large number of *product units*. However, it is important to define what is meant quite specifically because there are a number of different calculations that estimate similar characteristics but are, in fact, quite different. This can lead to confusion when interpreting the data, or even inappropriate use of the data.

The *mean* or *average* of a set of values is often calculated using the familiar total of the values divided by the number of values. In a sample, or a population, this calculation has to be modified to take into account the weight that should be given to each of the values so that the estimate is representative of the sample. Mean values are affected by the nature of the spread of the values that go into the calculation, and in particular are sensitive to the presence of values at the extremes. A mean provides information about the centre of the expected results only if the spread of values is symmetric (spread out fairly evenly on both sides of the centre).

Median

The *median* is also a measure of a typical value. This is the mid-point in the set of values that are being considered, once the values have been arranged in order of size. In a population, this is the point where 50% of the population is below this value, and 50% is above this value (also called the 50th percentile). The calculation of the median is not affected by extreme values. If the values are spread out fairly evenly on both sides of the median (i.e. fairly symmetrically), then the median and the mean will be almost the same value. The actual calculation of the median often needs to be modified, or weighted, to reflect the sample design.

2. Measures of spread

The terms *variability* and *variance* are often understood to describe the spread, range, or dispersion of the values. The nature of the spread of the nutrient values for your products is an important feature. Depending on the intended application of the nutrient values, this variability will play different roles. For example, when generating Nutrition Facts tables, variability in the amount of the nutrient will have an impact on whether a conservative label value is prudent to reduce the chances of failing to meet CFIA compliance criteria (see **Part 2, Chapter V,** page 64). Variability also plays different roles in the different approaches to determining nutrient values that are discussed in **Part 2, Chapter III** (page 36) and **Chapter IV** (page 54).

Like an average, there are a number of different specific calculations that all measure the dispersion (spread). When using reported values of variability it is critical to understand very clearly the nature of the values that went into the calculation. In general, the variance of a set of values is roughly based on the average distance (squared) of the values from the mean value. The specific calculations used often need to be modified to include aspects of the sample design so that it reflects appropriate sample weights. The *standard deviation* is also a common term reported; it is directly related to the variance, being the square root of the variance.

Variation and pooled units

In generating nutrient values from laboratory analysis, sometimes the individual units are pooled together, homogenized, and a single analytical result obtained for the combined units. This single result represents the average of all of the units included in the pool. Pooling is discussed more fully in **Part 2, Chapter III** (page 44)**.**

It is important to keep in mind how using the variance from a number of pooled units differs from the variance from a number of individual units. Measurements on individual units will have a certain amount of variability reflecting the spread in the individual units. However, a group of pooled results does not reflect the spread in individual units. Each pooled value is actually a mean and the extremes have been averaged out; thus there will be less variability in pooled samples.

The amount of variation that can be expected in pooled values depends on:

- the variance in the individual units that are pooled
- the number of units that are pooled

As the nutrient values from pooled units have substantially less variability than those found in the individual units, the variances cannot be used interchangeably.

Unfortunately when estimates of variability are given for laboratory results, published data or databases, the manner in which the individual units were combined may not be clear. As a result, it is difficult to know if the variances represent the results of pooled units, individual units or perhaps some combination. If variances from pooled units are used erroneously to represent the range in individual units, the calculations will underestimate the true variation,

leading to a sense that the nutrient in the product is more uniform than it actually is. This highlights the need to confirm how units were combined for analysis before using derived values such as variances.

Standard error

There is a third term that is sometimes reported with nutrient values. The term *standard error* is often used, implying *standard error of the mean.* It is used to understand the degree of certainty around an estimate of the mean that is being provided. In this use, it is interpreted as the standard deviation expected in the set of means from repeated random samples of a specific sample size.

Strictly speaking, any estimate (like a median, or a percentile) can have an associated standard error. If you encounter a standard error it is worth confirming the "*of what"* and "*how"* it was calculated. It can be used to understand the nature of the variance in the population of units itself. However, to do this arithmetic manipulation requires information on aspects of how the mean was constructed that are often not reported. This can be a problem in subsequent manipulation of the data.

> When you are evaluating nutrient values from any source, ask the originator of the values to clarify exactly how the values were calculated.

C. Characteristics of Portion Size

Nutrient values can be based on a number of different portion sizes (e.g. per stated amount of food, per gram, per 100 grams, per reference amount, per package). When reporting nutrient data it is important that the portion measure used for reporting the values is clearly stated. This portion measure may be required to:

- make correct inferences in product comparisons
- use calculations to convert from one portion size to another

Commonly, the portion sizes used for reporting will vary according to the application. In databases, the most common portion size is 100 grams, but some results may be provided per gram. For nutrition labelling purposes, there are requirements in the regulations[11] for how the portion size must be declared. It is more closely linked to the amount of food offered for sale or in a realistic serving.

When generating nutrient data for these different applications, you need to ensure that the information is presented on the declared amount.

D. Characteristics of Nutrient Units – One Nutrient, Many Units

Many nutrient names in a database appear identical to the names of nutrients that must appear on a label. However, some of them differ in their units, technical definitions or what they encompass. It is important to examine the nutrient values and ensure that they are correct for your application. Care should be paid to the units, how the nutrient is defined and how it is measured. Here are a few examples:

- Vitamin A is expressed in terms of International Units (IU) on US labels, Retinol Equivalents (RE) on Canadian labels, and Retinol Activity Equivalents (RAE) when referring to population nutrition studies and Dietary Reference Intakes.
- For labelling purposes, *total fat* is defined as "total lipid fatty acids expressed as triglycerides". In the CNF, *total fat* is defined as "total lipid including mono-, di- and tri-glycerides and polar lipids".

Appendix B illustrates more examples of the differences that you will find.

[11] See the table of core information following the Food and Drug Regulations, Section B.01.401
www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_b-text-1.pdf

III. Generating Nutrient Values by Sampling and Laboratory Analysis

As with any approach, if you choose to do laboratory analysis of your product, the steps you need to take can be grouped into three categories:

- Gathering the data
- Assessing the information
- Calculating the nutrient values

Each of these steps, as well as the type of documentation you should maintain, is outlined in detail in this chapter.

A. Gathering the Data

In this approach you gather the information on the nutrient content through physical testing of the final product in a laboratory. The approach involves:

1. Designing the sampling plan
2. Collecting and handling the sample units
3. Analyzing the sample units

Direct measurement can require a significant investment of resources. As a result, it is important to make the approach as efficient as possible, ensuring that you will get the maximum and most accurate information possible from the available budget.

This section will present some of the key issues to consider when undertaking product sampling and laboratory analysis, and help identify the steps that need to be included to achieve the desired quality of results. However, it cannot prescribe a sample design or sample size for your specific product. No single approach is best for all products or for all purposes. You can get help from other sources to determine your specific process:

- Consultants with expertise in statistical sampling can assist you. (Details on choosing a consultant are found in **Appendix C**.)
- Some reference documents, such as the US Food and Drug Administration's (FDA's) Nutrition Labeling Manual (1998),[12] include considerable detail on different types of sampling and provide some formulas.

There can be significant confusion in discussions about product sampling due to the language and vocabulary used. A glossary of terms related to product sampling can be found in **Appendix A**.

[12] *FDA Nutrition Labeling Manual*: vm.cfsan.fda.gov/~dms/nutrguid.html

1. Designing the sampling plan

All uses of nutrient values require accurate, representative data. The data should reflect accurately the entire product line, or groups of units, to which they refer. If all of the units of a particular product could be measured, then you would know exactly:

- the typical (average) nutrient values
- the range of values that can occur
- the aspects of the products and production that seem to affect these typical values and this range

However, it is impossible to test every unit, so you are faced with trying to establish this information from a relatively small number of units, or a *sample*. How many units of a product to choose, and which units to choose, form the basis of your *sampling plan*. Developing an appropriate sampling plan takes some care and planning at the outset. For example:

- You need to choose the right number of units to ensure cost-effectiveness.
- You need to consider the key factors that affect how to choose the units. Then the results will be as useful as possible and you will be able to generalize them to the entire product line.

> Appropriate sampling is of the utmost importance. No amount of subsequent analysis can compensate for a poorly selected sample.

What factors affect the sample design?

You need to gather all of the information available about your product (see **Part 1, Chapter II** (page 6) and **Part 2, Chapter II** (page 30). This step characterizes your products, providing important information to help choose which approaches to consider for determining nutrient content. The information you gather is also needed to design an appropriate sampling plan.

As the overall objective is to generate accurate values that are representative of the whole product line from a smaller number of sampled units, the specific units that are chosen must reflect as many as possible of the factors that affect the nutrient values. These factors might affect either the average or the range of values (i.e. *variability*) found in the product. Many of these have been discussed in **Part 2, Chapter II**. The factors might be under your direct control (e.g. processing aspects, such as temperature or time; formulations/recipes; suppliers; ingredients; species/variety), while others may be more difficult to control (e.g. impacts of season, weather, storage). It is important to identify as many of the factors as possible that affect the nutrient content of your product.

It is also very important to be able to identify which factors have the biggest impact as it may not be feasible economically to address those which play a small role. Using the information

in **Part 2, Chapter II** (page 30), you may be able to identify easily the factors and their influence. For example:

- The same product is produced in two different plants, which have different equipment, or different suppliers. As a result, the product lines may have a different average and range of nutrient values. If all of the samples for laboratory testing were selected from just one of the plants, the nutrient values generated may not be a good representation of the products from the other plant, and consequently, the product line as a whole.
- In some cases, products with the same common name and brand name may be produced with two different formulations in two different plants. This situation needs to be evaluated to determine if there is an effect on the nutrient values in the final product. For example, if the change in ingredients has a significant effect on some nutrient values, you would need to label conservatively for those declared nutrients.

On the other hand, you may not have information available to be able to describe adequately the factors that affect nutrient values and their ranges for your product. In this case, it may be necessary to:

- Review and document in detail the characteristics of processing or conditions of production involved over the whole product line (including growing conditions, recipes, ingredients, sources, process control factors).
- Assess the impacts of these characteristics on the typical value and ranges of the product line. You can do this by:
    - reviewing information on similar products available in general literature, historical production records, and/or commodity association information
    - undertaking a small study (or a *pilot*) of products to help determine the factors that need to be considered in sampling. This may involve collecting a limited number of units in a structured way, followed by laboratory analysis.

How do you develop the sample design?

Once you have a good understanding of your product and the key factors that affect the average and the range of nutrient values, you can make an informed decision on how to proceed with sampling. The sample design can be developed so that:

- the units are chosen in such a manner that they are representative of the population of the products, and can be used to provide sound estimates that can be generalized
- the number of units is large enough to encompass to some degree the identified sources of variability and provide estimates with the desired level of certainty

After the factors that cause nutrient values to vary have been characterized, the next steps to design the sample plan include:

- identifying the complete population of product units to which the nutrient values are to pertain and from which the sample will be chosen (called a *sample frame*)
- determining which units are to be sampled
- determining how many units are to be sampled

Identifying the sample frame may seem trivial; however, it begins a concrete process of gathering the documentation that will be needed to move on to the next two steps. This documentation will also play a role in determining how the data will be treated arithmetically to construct the appropriate representative estimates. The documentation would include:

- identity of all of the units that are pertinent
- the production characteristics, conditions and factors that affect nutrient values (such as plant locations, nature of the lots, geographic regions for growers, species, feeding practices, production size, season)
- the number of units produced under each of the different conditions

Determining which units and how many units to sample can be quite challenging. The decisions can depend on the complexity of the different factors that impact the nutrient values; the degree of precision needed for the estimated nutrient values; and the resources available for sampling and testing. For some purposes, such as nutrition labelling, the size and nature of the sample design may be affected by the compliance test threshold outlined in the CFIA *Nutrition Labelling Compliance Test*.[13] Some designs are very elaborate and large, while others are simple and compact. At this stage in developing nutrient values you may want to consult with a statistician or a quality engineer to help with the sampling plan. (Some information on hiring a consultant can be found in **Appendix C**.)

What are the types of sampling?

Regardless of the size of sample chosen, it is recommended that the choice of units be made in a statistically sound manner that will allow interpretation of the results for the entire product line.

Some types of sampling do not allow for this generalization. An example is sampling in which the units have been chosen purely because they are convenient or expedient, but cannot be related back to the product line as a whole.

Instead, it is recommended to use sampling plans that employ a probability-based approach whereby every unit has a chance to be selected, and this chance can be calculated. *Probability sampling*, properly implemented, will allow appropriate treatment of the resulting data to provide representative estimates, and will allow estimation of the degree of certainty for that estimate. Samples that are not probability based will not provide statistically sound inferences to the whole product line.

Sample designs can be very simple and straightforward or they can involve a number of different steps and stages to arrive at a complex set of directions for the unit collection. The information gathered about your product (as discussed in **Part 2, Chapter II**, page 30) will help in devising the best type of sample design for your product: some types of designs are more cost-effective than others, depending on how the key factors that make your product vary have been incorporated into the plan. This can affect both how many units are selected and where the units are selected; as a result these decisions often are made together. Different

[13] CFIA *Nutrition Labelling Compliance Test*: www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

options for sample designs can be considered, ranging from simple to complex, and the cost-effectiveness weighed.

An example of a commonly used type of sampling suitable for many food products is to first choose a large number of lots representing different geographical locations, plant shifts, production runs, and so on. Then individual units of the product are sampled from each of the different lots. This type of sampling when used in conjunction with suitable *pooling* of the individual units (see page 44) can be a very cost-effective way to derive sound, representative nutrient values that reflect key sources of variation.

How many units do you need to sample?

This is often the heart of discussions about sample plans. To answer this, you need have some idea of how precisely you want to estimate the nutrient values. In general, greater precision will require larger samples. With too few samples there is a greater risk that key factors that influence nutrient variability will not be reflected in the sample design. However, a sample size that is much larger than needed is not cost-effective.

Statistical formulas can be used to determine the number of samples needed to estimate a mean with a given precision and certainty, for a product line with a known amount of variability. These formulas, found in most sampling or statistical books, should be adjusted to take into account the impact of the type of sample design chosen (factors known as *design effect*). These formulas can be modified to include cost parameters as well. The statistical formulas also require an estimate of the amount of variability in the product line overall. This estimate may be derived from a small representative (*pilot*) study. If your type of sampling takes advantage of pooling individual units (described on the next page), then more individual units can be chosen, representing a broader range of conditions.

The laboratory may also require a minimum amount of food for the analysis; this would also have an impact on the number of units needed. The laboratory should be able to tell you this information before the sample is designed; this constraint then can be built into the sample design.

How precise an estimate do you need?

This decision can be influenced by a number of factors, with the intended use of the nutrient values being the most important. If the nutrient value is being generated for submitting to a database, providing values as an ingredient to another manufacturer or reporting in a journal, then levels of precision and certainty may be prescribed in standards. These standards may be stated in terms such as the expected chance that the true average nutrient value lies within an interval of a specified width; or as an expectation about the relative size of the uncertainty around the estimate. Such prescribed standards can be built into the usual statistical formulas to help estimate the sample size needed to meet them.

If the nutrient values are to be used for package labelling, then the compliance test parameters set out by the CFIA,[14] and the likelihood of meeting these performance standards, can affect the number of samples needed. These standards may refer to limits on claims, or to

[14] CFIA *Nutrition Labelling Compliance Test*: www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

compliance tests in general where you wish to generate a label value with a high likelihood of being deemed in compliance.

What impact does pooling of units have on sampling?

It is important to consider the laboratory analysis plan when you are designing the sample plan. For example, it may be possible to take the individual product units and group them into a number of pooled units, and then conduct laboratory tests on the pooled groups. When units are pooled for laboratory analysis, each resulting nutrient value reflects the average of the units that went into the pooling. This is a cost-effective way to measure the average and it allows you to provide minimum amounts of foods needed for some nutrient analysis; however, you lose information about the variability of the individual units.

Because you lose some information, it is important to form the pooled groups in a manner that is less likely to hide the impact of variability. *Compositing* and *commingling* are two terms are often used to describe different ways to pool units.

Composites mix units that were produced under similar conditions, such as within an orchard, from the same herding region or from the same production lot. Units produced under different conditions, or reflecting different factors that have an impact on the nutrient values, are not pooled together. The mixing of "like" units preserves the information about the factors that make the nutrient values vary. When the factors used for forming composites represent those used in the sample design, the appropriate sampling weights can be taken into account to calculate a representative nutrient value.

This is in contrast to *commingling* where units capturing different factors are mixed (such as from different breeds, over different factories or over different lots), so the resulting laboratory analysis reflects an average over the different factors. The information on the nature and magnitude of nutrient differences due to these factors is lost. The sample weights for the different factors cannot be applied so the sample design cannot be taken into account in the calculations of means and variances.

> Some care must be taken when deciding how to pool units.
>
> You need to understand your product and process, and determine which factors are significant.

Considering the pooling that you might use at the laboratory analysis stage, can have a significant impact on the sample design. It may allow you to include a larger number of individual units in the sample, collected under a broader range of conditions for the product (such as lots and locations), which would provide more certainty about the average results at a modest increase in cost.

You would need to decide how to pool and how many units to pool. For most applications, it is advisable to composite, rather than commingle, in a way that preserves the differences between the different conditions from which the units were chosen. For example, individual

units chosen from different production lots should be pooled within the same lot so that the variability that the different lots represent is not lost.

In the specific case where values are being generated for a Nutrition Facts table, it should be recognized that CFIA will test 12 samples, pooled in 3 groups of 4 to determine compliance of the label values with the regulations. These samples will be taken from a single randomly chosen lot. As a result, it is very important for you to attempt to capture as many factors as possible that will make the lot averages vary when deriving label values to ensure a good chance that any one lot average as tested by CFIA will be in compliance. This means that many lots under different conditions need to be included in the sampling, so that the label values reflect the whole product line.

There is more than one way to approach sampling. To design a sampling plan and determine the sample size that suits your budget, you may need to seek the advice of a statistician, quality assurance professional or industry association.

Once a decision is made and sampling is undertaken, details about implementation should be documented to ensure the appropriate treatment of the data as well as follow up of unusual results. Proper documentation will also ensure that the design can be repeated in the future.

2. Collecting and handling the sample units

Once your sampling plan has been determined, it is important to collect the sampled units in an organized manner. Legible, permanent labelling of each food unit is critical. Whether the units are collected by quality assurance staff at the plant, by laboratory personnel at retail level or in other situations according to your sample design, it should not be possible to remove marks by rubbing, washing or freezing.

In addition, documentation of the food sample should include:

- identity of the person responsible for each step (e.g. sample collector, shipper, receiver at the laboratory)
- identification number (assigned by sampler)
- name of the product, including product variety, lot number or code, and possibly ingredient information
- size or amount of product collected
- place, date and time of collection
- name and address of the grower, processor, distributor, shipper, supplier, retailer, and so on
- description of the dispatch information (packing, shipping and handling) sent to the analytical laboratory
- shipping medium (such as plastic tub, parchment, foil, or polyethylene bags) and transport conditions
- any auxiliary information that will be needed in the statistical evaluation (e.g., stratum size, cluster size)

This information should accompany the sample and the analytical results through all stages, from sample pick-up to reporting of results.

> It is crucial to retain the physical integrity (physical characteristics, nutrient content) of the laboratory sample. The best analytical capability available cannot restore the physical integrity of the laboratory sample if these or other qualities have been compromised during collection, handling or shipping.

3. Analyzing the sample units

Analysis of nutrients in food is a complex process. It requires appropriate equipment and expertise. The selection of a laboratory and the methods of analysis it will use are critical to obtaining accurate values. You want to ensure that the results obtained from laboratory analysis accurately represent the product tested. It is therefore important to minimize the variability in the laboratory measurements by choosing an experienced laboratory.

Minimizing variability of laboratory measurements

How do you select a good laboratory?

You may use an in-house laboratory or contract out the analysis of your products. Several issues are important to consider:

- The laboratory should be able to demonstrate that it is technically competent by indicating accreditation by the Standards Council of Canada (SCC). Accreditation will also ensure compliance with internationally accepted standards for facilities, equipment and personnel.
- The laboratory should demonstrate experience in food testing and use of methods that have been validated for the food *and* the nutrient you want to have analyzed.

What is an accredited laboratory?

If you choose to use an outside laboratory, CFIA recommends those accredited to ISO 17025 standards by the SCC. Laboratories in other countries are accredited to the same standard. In Canada, ISO 17025 CAN-P-4D standards are embodied in the Program for the Accreditation of Laboratories/Canada (PALCAN),[15] as described in the *Guidelines for the Accreditation of Agricultural and Food Products Testing Laboratories*.[16]

Examples of criteria set out in the ISO 17025 CAN-P-4D standard include:

- Samples are properly logged, stored, analyzed and archived.
- Integrity of the data is supported with a complete history of how the samples have been handled (e.g. compositing of laboratory samples, preparation and storage).
- Analysts are trained appropriately and tested for proficiency.
- Appropriate methods are used and validated.
- Equipment is calibrated and maintained.
- Internal quality assurance programs are followed.
- Results are checked for accuracy and reasonableness.
- The laboratory passes standards for tests of proficiency.

[15] PALCAN can be found on the SCC Web site: www.scc.ca

[16] Standards Council of Canada: *Guidelines for the Accreditation of Agricultural and Food Products Testing Laboratories*. CAN-P-1587, 2003
www.scc.ca/en/publications/criteria/labs/agriculture.shtml

The laboratory should also provide access to technical personnel who can answer your questions and provide all of the information required. You may want to contact your industry association, as many of them have arrangements with laboratories for nutrient analysis. In addition, a quick search of your telephone book will usually yield a number of local laboratories. Not all of the laboratories listed will be experienced in testing nutrients in food, so you will need to confirm that the laboratory can meet the criteria discussed above and outlined in more detail in **Appendix D**.

The SCC Web site[17] lists all of the laboratories that are currently accredited for analytical testing in Canada. Their extensive list includes both government and commercial laboratories accredited for various chemical, physical and microbiological tests.

- Most government laboratories do not analyze samples for non-government applications, so you will need to search for commercial laboratories.
- Not all laboratories perform analyses for food chemical composition, so you need to determine the scope for which the laboratory is accredited. This can be searched on the SCC Web site. Under Programs and Services, choose the Laboratory section from the left-hand menu, then select Accredited Clients, and key in the words "agriculture and food and chemical". Information on a number of laboratories will be provided.
- You can also use your commodity as the search criteria (e.g. "cereals and chemical").
- Once you have obtained the list, you should look at the details of each laboratory to ensure that they are experienced in testing your type of product. Cross-referencing this to laboratories you know are in your area (from your telephone book) will speed your search.

Are the methods they use important?

CFIA recommends using the methods of analysis published in the most recent version of the *Official Methods of Analysis of AOAC INTERNATIONAL*.[18]

For information on the methods of analysis used by CFIA and additional sources for methods, see Appendix 4 of the CFIA *Nutrition Labelling Compliance Test,*[19] which lists methods recommended for the core nutrients.

If you require analysis of other nutrients or if your laboratory proposes to use a different method, they must be able to demonstrate the validity of that method and provide written assurance that the results are comparable to those obtained by recognized methods. Regardless of the source of the method, it should be validated for the particular type of food being analyzed.

[17] SCC Web site: www.scc.ca

[18] For information on the *Official Methods of Analysis of AOAC INTERNATIONAL:* www.aoac.org/pubs/oma_revised.htm

[19] CFIA *Nutrition Labelling Compliance Test, Appendix 4* www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

Do you need data on all nutrients?

Many laboratories offer package prices for particular combinations of analyses such as proximate components (fat, protein, carbohydrates, ash and moisture); fatty acids; basic minerals; and the 13 core nutrients for nutrition labelling. Thus it may be cost-effective to analyze your food sample for all of the nutrients included in the package price from the same sample. However, there are exceptions. If you substitute an ingredient, you may test only for the nutrients that are affected; or if a product is known not to contain a particular nutrient(s), you may choose not to test for that nutrient. For example:

- Products (e.g. cereals, vegetables) that do not contain animal fats will not contain cholesterol.
- Most milks, yogurts and meats do not contain dietary fibre.
- Most muscle meats do not contain Vitamin C.

What else do you need to discuss with the laboratory?

Prior to sending samples to the laboratory you have selected you should discuss your requirements with the laboratory personnel, obtain price quotes and provide detailed instructions to the laboratory. You first need to make the following decisions:

- How should the sample be sent to the laboratory?
  - The laboratory analysis depends on the integrity of the sample, so consideration should be given to the stability of the nutrients and the storage life of the product. The laboratory should be able to advise you on your options.
- How would you like the results reported?
  - The report should include the raw data. The same nutrient may be reported using different units of expression (e.g. grams, µg, RE) so care must be taken to ensure that the data you receive are expressed in the appropriate units and definitions for your application. (Refer to **Appendix B**.)
  - Some manipulation of the results may be required if the results are not reported for the portion size you need. You may wish to provide the serving size or ask for results per 100 grams.
  - If the report includes arithmetically treated data, ensure that the treatment will be appropriate for your application.
  - Will they conduct duplicate analyses and if so, how will these be included in the calculations?
  - Will they provide an estimate of variability or range?
  - What quality review is done on the data prior to calculations?

B. Assessing the Information

Assessing the information involves reviewing the laboratory results. It is important to obtain and review the unrounded values for each nutrient analyzed by the laboratory, even though some laboratories may be able to provide summary information, calculated values or camera-ready Nutrition Facts tables. A detailed checklist is provided in **Appendix G**. The following chart outlines a few simple checks you can do.

A Few Simple Ways to Review the Laboratory Results	
What to do	**Details**
Look for missing values	• Confirm that no results are missing. There should be a laboratory result for every analyzed unit or pool of units. • If there are blanks or zeros in the raw data, check with the laboratory about what these mean so you can take it into consideration properly when you use the data. They could represent very different information about the sample (e.g. levels below the analytical limit of detection, values deleted because they appeared unusual, true zeros; or they could indicate that a sample was dropped and no value is available).
Review any outliers	• Review results that appear to be unusually large or small and confirm with the laboratory what steps were taken to verify them. Unusual values can be very informative; for example, they may actually reflect true variation in the product or result from outside influences. • Check what the usual practice is of the laboratory for reporting unusual results and results that are below the analytic limits of detection.
Check reporting of duplicate values	• Ascertain if the laboratory includes duplicate (or triplicate) analyses, and how these are reported (e.g. the reported results may be averages of the duplicates, or one of the separate results).
Look for rounding	• If the values all appear to end in rounded values (0, 2 or 5), check with the laboratory about where possible rounding might have occurred.
Confirm the reporting units	• Confirm the reporting units for the nutrients as well as the portion size (e.g. results reported per serving size, per 100 grams).
Add up the proximates	• Ensure that the sum of the proximate components (fat, protein, carbohydrates, ash and moisture) is close to 100%.
Check the totals of fat and carbohydrate	• Check that the sum of fat components does not exceed the amount of total fat. • Check that the sum of carbohydrate components does not exceed the amount of total carbohydrate.
See if label values seem reasonable	• If the laboratory provides values for Nutrition Facts tables, compare the raw values with the label values to see if they seem reasonable. (The label values may be slightly different as they will have been rounded or treated according to the rules that pertain to nutrition labelling.)

C. Calculating the Nutrient Values

One of the greatest strengths of the data obtained from sampling and laboratory analysis is the flexibility that they afford. The same data can be treated arithmetically in different ways for different uses.

For example, if you are a supplier of an ingredient, you may want to use the same laboratory data to provide results for a number of uses:

- Product specifications for customers may require averages per 100 gram, with estimates of overall variability and sample sizes for the laboratory testing.
- An industry or association database may require an average per gram, with your product included as part of a generic estimate combined with those of other producers.
- Nutrient labelling for your own retail use requires the typical nutrient amount in rounded label values given per serving size and in percent Daily Value (% DV) given per serving.

In each of these cases it is critical to have accurate, valid underlying data. A sound sample plan with a sufficient number of samples should provide data that can be used for all of the above purposes, by employing slightly different arithmetic treatments of the data.

The arithmetic treatment of the data for all of these uses must take into account the nature of the sample plan:

- If some parts of the product line had more emphasis or representation in the sampling (relative to their proportion of the product), then this will have to be taken into account in the development of the averages or variances.
- If the sample design was relatively simple then these calculations are quite straightforward and can usually be done with a hand calculator or a simple spreadsheet.
- If the sample design is more complex (perhaps with clustering, stratification, or sampling in a number of stages), then you may need the assistance of a statistician and more elaborate formulas in spreadsheets or specialized software.

The *FDA Nutrition Labelling Manual* (1998)[20] provides formulas for means and variances for simple sample designs from production lots (Section 5-1) as well as formulas for stratified designs, which is just one particular type of more complex sampling (Post Section 5-7). You will need to tailor your calculations to your sample design.

All of the calculations will need to take portion sizes into account. The laboratory results will need to be converted from the reported portion to the relevant serving size required for the intended use.

[20] *FDA Nutrition Labeling Manual*, Section 5-1 and Post Section 5-7
www.cfsan.fda.gov/~dms/nutrguid.html

The treatment of data specifically for nutrition labelling is discussed in detail in **Part 2, Chapter V** (page 64).

D. Keeping Detailed Records

It is important to keep records of your ingredient information, product formulation and nutrient content calculations. It may be possible to incorporate this into your software program or it may be more efficient to use an electronic spreadsheet. You should also document how the sample units were collected and combined, methods of analysis, the date the analyses were done, and who conducted the analyses.

Some of the information that should be kept **for a minimum of two (2) years** is outlined in the chart on the following page.

Information to Be Kept for a Minimum of 2 Years	
Item	**Information to be kept**
Finished products	• A precise description of the product, including UPC and lot numbers, where applicable • Product formulation or recipe, including ingredient suppliers and backup documentation • Processing and packaging details including equipment used, times, temperatures and pH • Records of any deviations from standard procedures and protocols such as ingredient substitutions, changes in water and fat content, and other chemical interaction • Rationale regarding any decisions made during nutrient calculations
Sampling frame	• Identity of all units included in composites • Production characteristics, conditions and factors that affect nutrient values (plant locations, nature of the lots, geographic regions for growers, species, feeding practices, production sizes, season) • The number of units produced under each of the different conditions
Food sample	For each sample unit: • Identity of the person responsible for each step (e.g. sample collector, shipper, receiver at the laboratory) • Identification number (assigned by sampler) • Name of the product, including product variety, lot number or code, and possibly ingredient information • Size or amount of product collected • Place, date and time of collection • Name and address of the grower, processor, distributor, shipper, supplier, retailer, and so on • Description of the dispatch information (packing, shipping and handling) sent to the analytical laboratory • Shipping medium (such as plastic tub, parchment, foil, or polyethylene bags) and transport conditions • Any auxiliary information that will be needed in the statistical evaluation (e.g., stratum size, cluster size)
Documentation	• Identity of the laboratory conducting the analyses • Results of laboratory analysis • Documentation from the laboratory, such as details of the methods used, history of how samples have been treated, and results of analytical quality control performed during the relevant period • Individual records and summary results

IV. Generating Nutrient Values from Existing Sources

Another way to generate nutrient values is to determine them indirectly from existing sources. A number of different sources, each having different specificity, can be used to calculate nutrient data for end products or recipes from ingredient information. The first step is to collect data on your ingredients and the nutrients of interest. Once you have determined that the data you have are suitable for your application, you can combine the data on each ingredient to give you total values for each nutrient in your product. This can be fairly simple if your product has few ingredients and little processing, or can be quite complex.

Each of these steps as well as the type of documentation that you should maintain is discussed in this chapter.

A. Gathering Information on Your Ingredients

In this approach your first step is to collect data on your ingredients and the specific nutrients of interest. It is also important to determine the effects of processing on each of these nutrients.

1. Information on ingredients

Nutrient information can be divided into two broad categories:

- Ingredient-specific information can be obtained from the supplier of the specific ingredient or from certain databases that specify the nutrient information according to the specific manufacturer.
- Generic information, which is not brand-specific or specific to any one manufacturer or supplier, can be found in various food composition databases.

A database is a collection of data brought together and stored in some manner for future retrieval. It could be as simple as a file folder containing information on each ingredient, or as complex as a set of relational electronic files. A database can contain ingredient-specific data, generic data, or a combination of both. There are several types of databases, including databases that are company-specific, government reference databases, and commercial databases (each described below). It is important to note that any of these types of databases may not contain all of the nutrients in which you are interested.

Company-specific databases

Company-specific databases may be specific to an ingredient supplier or a manufacturer. The databases used by an ingredient supplier may contain information about its products only. A manufacturer's database may be a compilation of nutrition information on all specific ingredients that are used in its products as well as nutrient information on its finished products.

The purpose of a company-specific database is to collate nutrient data about a specific ingredient or food and allow for the calculation of values that will take into account the nutrient changes due to processing. For example, a manufacturer may collect data from each of its suppliers on each ingredient used, and use the data to calculate the nutrient values in its end product.

Government reference databases

The primary purpose of government databases such as the CNF[21] and the USDA-SR[22] is to provide standard reference data to all researchers and health professionals who are assessing the dietary intake of the population, thus increasing the degree to which their results are comparable. The databases can also be used by dietitians and the public to assess individuals' eating habits.

Reference databases can also be created for other purposes, such as the database created by the US FDA to provide nutrient values for the voluntary labelling of the 20 most frequently consumed raw fruit, vegetables and fish in that country.[23] The data in this type of database could be the same as in other generic databases of foods consumed in the same area. However, the final values could be different as they may be rounded values, as well as take into consideration nutrition labelling compliance test standards.

Commercial databases

A number of custom commercial databases also exist. They contain generic information from the CNF or USDA-SR as well as data from other sources such as industry brand-name data. As these databases contain both generic and brand-specific data, it is important to ensure that the data you choose to use will reflect your actual ingredients or products. The characteristics of the values in these databases may vary depending on the original source of the data.

It is important to understand the distinction between a food composition database and a nutrient analysis software program. Regardless of its size or complexity, a database is simply a collection of nutrient data recorded in some manner. Retrieval of these data, if stored electronically, can be difficult without the assistance of database management software. As a result of this many commercial custom databases come packaged within a software program. As the only way to access these data is through the software, the distinction between the data and the software tends to become blurred. Nevertheless you should assess the data contained within the package separately from the software features manipulating this data. Both the data and the software must match your intended application.

The ease of access and the availability of brand name data make these programs very popular for individual diet assessments by both dietitians and the general public alike. Some care should be exercised when considering the brand name foods as factors such as industry processes, changes in products on the market and their nutrient profile, and availability of new ingredients can cause this data to become quickly out of date. For example, the fatty acid

[21] CNF: www.healthcanada.ca/cnf

[22] USDA-SR: www.nal.usda.gov/fnic/foodcomp/Data/SR17/sr17.html

[23] See US Code of Federal Regulations Title 21, Part 101.108, Appendices C and D www.access.gpo.gov/nara/cfr/waisidx_04/21cfr101_04.html

profile for many margarines on the market has changed many times over the past 10 years while the margarine still carries the same brand name.

The utility of these various databases will depend on your application:

- Product-specific information is appropriate for generating nutrient values for labelling and advertising purposes where the values must comply with precise expectations and standards on how they should accurately reflect the content of the final product.
- In addition to dietary assessment, generic information compiled in reference databases may be appropriate for the calculation of recipes where the ingredients used may vary.
- Generic information compiled in a special reference database may also be appropriate for the labelling and advertising of products that are sold as a generic category of food (e.g. apples or round steaks).

Data in a company-specific database will tend to be very product-specific. In contrast, in a reference database the values will tend to be generic as they generally are developed from data coming from a variety of sources and represent a group of products of the same type commonly consumed by a population. For example:

- A reference database will most likely list chocolate chip cookies, rather than a chocolate chip cookie manufactured by a specific company. The values reflect a generic compilation of the items most available to the consumer of the food as described. Therefore they cannot be expected to be identical to any single unit, brand or ingredient.
- A generic database such as the CNF will incorporate data that represent a compilation of the top millers of retail all-purpose flour sold in Canada.
- A company-specific database will contain a specific manufacturer's or supplier's flour milled to specifications suiting a particular formulation.

Both the database and the software used to retrieve the data must match your intended application.

2. Information on effects of processing

Many events occur during the processing of food products: moisture increases or decreases; nutrients are destroyed or washed away; fat may be lost or absorbed. The most important tools for calculating nutrient values from the data on your specific ingredients are your understanding of what happens to the ingredients during processing and the ability to reflect the impact of processing on nutrient content.

Accurate calculation of nutrient values for a product from the ingredient data depends on:

- accurate values for all relevant nutrients for all ingredients
- adjustments of fat and water to reflect their changed proportions in the product
- modifications of vitamin and mineral values in each ingredient to reflect the processing involved

When dry ingredients are simply combined and not further processed, the calculation may be very straightforward and adjustments of nutrient values are not required.

Changes in water can significantly affect nutrient content per unit of weight. If the water content of one or more raw ingredients is incorrect, or the loss/gain of water during processing is not accounted for properly, the concentrations of nutrients calculated for the finished product will be incorrect.

The *USDA Table of Nutrient Retention Factors, Release* 5 (2003)[24] is a good source of information on retention of vitamins and minerals in processed foods. Applying these factors to the amounts of vitamins and minerals in raw ingredients generates approximate amounts likely to remain after processing. For more information on applying retention factors, see **Appendix E**.

Successful calculation of nutrient values requires expertise. You may choose to perform nutrient calculations in-house or to contract them out to a dietitian or food scientist with expertise in calculations of product formulations using an appropriate software program. Be sure to ask what type of software they plan to use, as not all types do a good job of accounting for processing factors. Additional information on choosing a consultant can be found in **Appendix C**.

[24] *USDA Table of Nutrient Retention Factors*: www.nal.usda.gov/fnic/foodcomp/Data/index.html#retention

B. Assessing the Data

It is important to assess both the quality and the specificity of the data you will be using. The source of the data used in any calculation must be well understood. It is important to know if the data are product-specific or generic. Many considerations will apply in either case, but some will be specific to the source.

You need to ensure that the information you have is accurate. You should review all incoming data and resolve any discrepancies such as the precision to which the data are reported (i.e. rounded values or laboratory values) or whether the values seem reasonable compared with the initial point of reference you established.

You may want to request laboratory analysis to validate the nutrient values in your ingredients. You also can validate your final results using laboratory analysis of your finished product, following the sampling and analysis approach described in **Part 2, Chapter III** (page 39). If values are missing for some nutrients, you will need to have the samples analyzed. If you are not obliged to report a nutrient, you may leave it out of your calculations if critical information on raw ingredients is missing.

1. Supplier information

When calculating nutrient values based on ingredient information, it is generally preferable to use the nutrient information from your ingredient suppliers, as this is more likely to represent the product you are using. Some suppliers of fresh fruits and vegetables, meat, poultry, fish and seafood, and alcoholic beverages are not required through federal regulations to provide nutrient information. You may want to add this requirement to your contract, or you can consult alternative sources of information, such as generic databases, for those foods.

The values provided by your suppliers may come from their own databases of laboratory analysis data, from a calculation using ingredient information, or from values taken directly from a generic reference database. Data from direct laboratory analysis is preferable, as it will represent the actual ingredient that you are using and will allow you to further manipulate the values in a database. It is advisable to obtain more information on how the supplier's values were developed and what they really represent:

- Are the values specific to your ingredient or to a similar ingredient, or are they generic values for a mix of products? If the values represent the exact ingredient you are using, your final values are more likely to represent your product.
- Were enough samples used to generate the values?
- Did the samples reflect the current products, ingredients and test methods?
- Did the sample design capture the key sources of variation?
- Is the value presented an average or median?
- Is there any indication of the variability, or the range?
- Are validation data available to show that the numbers are likely to be correct?

In addition, nutrition information provided by suppliers must "be stated with a degree of precision that corresponds to the accuracy of the analytical methodology used to produce the information".[25] Information rounded according to the rules of declaration in a Nutrition Facts table would not be acceptable because of the additional approximation it would add to your own calculations.

- For example, if your product contains five ingredients that each contain 0.4 g fat/serving, each ingredient would report zero amounts of fat in its individual Nutrition Facts table, due to the rounding rules. However, when you combine those ingredients, it would not be correct to report zero fat, as you would likely have more than 0.5 g fat in your finished product.

2. Reference databases

In some cases, generic information from a reference database is acceptable, especially if the ingredient or nutrient does not exhibit much variability. Granulated sugar and butter are examples of ingredients that do not vary significantly from one supplier to another, their profiles being defined in Canadian food regulations.

Reference databases are accompanied by extensive documentation describing the type of data (analytical, calculated, imputed) and the source of the data. They also usually indicate the possible range or variation around the mean or median. Although the presentation of this documentation varies among national databases, all follow established international standards[26] for collecting and relaying this information wherever possible. All of the documentation should be examined by the user to assess whether the data are suitable for a particular application.

Before using generic information in your calculation, you should verify the following features:

- The information should be available for all nutrients of interest. If a record is missing, it should be noted; a zero should not be used unless the amount is zero.
- The data should be up-to-date and reviewed by personnel with knowledge and experience in the area.
- The source of the data should be recorded and available.
- The database values should be based on analytical data, unless generic data are sufficient (as in the case of sugar or butter).
- The units of measurement should be metric, for consistency when combining ingredients.

Generic information is also acceptable for providing nutrient information to consumers for a generic category of products, such as pink grapefruit. Yet, the values must be representative

[25] Food and Drug Regulations, Section B.01.404(3)(IV)
www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_b-text-1.pdf

[26] International Nutrient Databank Directory
www.medicine.uiowa.edu/gcrc/nndc/NDB%20survey%20final%20version%2011-04.pdf

of the category of foods. Because the nutrient content of these products may exhibit important variation, final values may need to be adjusted for nutrition labelling purposes (see **Part II, Chapter V**, page 64).

3. Commercial databases

Information from a commercial database may be used with caution for some cases where the ingredient or nutrient does not exhibit much variability. You should check the source of the information you intend to use. Commercial databases tend to supply one value with little information about the data type, source, or representative sample sets. Many will provide the source as "from USDA" or "from Heinz", but for actual information on where USDA obtained the data or what kind of sampling went into the Heinz values, you have to consult these original references. Data from one record are often "borrowed" or extended to another similar food to avoid missing values, with no explanation of the standards or assumptions for doing so.

C. Combining the Data

You will need to customize your own database of ingredient information. The complexity of this task depends on your product, the number of ingredients and the processing steps. The task could be quite simple, such as keeping a file folder of information on each ingredient. It could also be more complex and benefit from the use of a commercial software package to make the calculations more efficient, help in accounting for the processing effects, and make it possible to fill information gaps with generic information from a commercial database.

Calculations for determining the nutrient value of a finished product generally involve adding the nutrient contribution of each ingredient and then making allowances for processing effects (such as moisture loss from baking or fat addition from frying).

1. Entering the ingredient information

Using a spreadsheet

For a product with a relatively simple formulation, you can make a chart such as the one shown below. For all ingredients, you enter the amount of each nutrient of interest in a set amount (e.g. per 100 grams) and convert this to the final amount in your product, then simply sum the contribution of each ingredient. You can then convert this to the amount per serving.

Sample Chart for Tracking Ingredient Information

Nutrient	Product: Dry Cake Mix									
	Flour Amount		Sugar Amount		Baking powder Amount		Salt Amount		TOTAL Amount	
	In 100 g	In product	In 100 g	In product	In 100 g	In product	In 100 g	In product	In product	Per serving
Weight (g)	100	300	100	340	100	12	100	6	658	60
Calories (kcal)	360	1080	400	1360	137	16.4	0	0	2456.4	224.0
Fat (g)	1	3	0	0	0	0.00	0	0	3	0.3
Saturated Fat (g)	0.35	1.05	0	0	0	0.00	0	0	1.05	0.10
Trans Fatty Acid (g)	0	0	0	0	0	0.00	0	0	0	0.00
Cholesterol (mg)	0	0	0	0	0	0.00	0	0	0	0.00
Sodium (mg)	2	6	0.9	3.1	3579	429.5	38758	2325	2764.0	252.0
Carbohydrates (g)	75	225	100	340	34.2	4.1	0	0	569.1	51.9
Dietary Fibre (g)	3	9	0	0	0	0.00	0	0	9	0.8
Total Sugars (g)	1	3	100	340	0	0.00	0	0	343	31.3
Protein (g)	11.6	34.8	0	0	0	0.00		0	34.8	3.2

For products that are more complex (e.g. if a product has many ingredients or if you need to take into account processing effects such as retention factors), it may be useful to use an electronic spreadsheet or computer program that will help you to do the calculations more efficiently.

Using a commercial software program

While software programs can make the job of calculating nutrient values easier and more efficient, they must be selected carefully in accordance with your needs. Note that they are useful for nutrition labelling only if they enable you to add your supplier-specific information to the database. The following are some of the other critical features that should be included:

- You should be able to customize your own ingredient database by adding nutrient data and other pertinent information on desired foods, supplier ingredients, and so on.
- As nutrient values may change during storage or processing, there should be provision for incorporating retention factors, and their source should be noted. Retention factors are discussed in more detail in **Appendix E**.

A few other features that may assist you include:

- the ability to add other nutrient fields and notes
- protection against overwriting data when the software is updated
- ingredient name fields large enough to permit meaningful description
- the ability to export data easily into a spreadsheet program

Further details on the critical features to consider when choosing databases or software can be found in **Appendix H**.

2. Entering the formulation information

Once all of the ingredients are entered into the database, you can enter the specific formulation for the product of interest. You must enter all ingredients so that the complete formulation is included. If required, you should adjust nutrient values by applying retention factors for vitamins and minerals that reflect your processing methods. Fat and moisture content and final weights need to be adjusted in accordance with your processing conditions.

The next step is to calculate unrounded values per 100 grams of finished product. It is important to check whether these values appear reasonable. One way to do this is to compare these values with those for similar products.

Further treatment of the data specifically for nutrition labelling can be found in **Part 2, Chapter V** (page 64).

D. Keeping Detailed Records

It is important to keep records of your ingredient information, product formulation and nutrient content calculations. It may be possible to incorporate this into your software program or it may be more efficient to use an electronic spreadsheet. In any indirect method, it is important to record the sources of your information, how the effects of processing were taken into account, and whether laboratory analysis was used to validate the results.

Some of the information that should be kept **for a minimum of two (2) years** is outlined in the chart below.

Information to Be Kept for a Minimum of 2 Years	
Item	**Information to be kept**
Finished products	• A precise description of the product, including UPC and lot numbers, where applicable • Product formulation or recipe, including ingredient suppliers and backup documentation • Processing and packaging details including equipment used, times, temperatures and pH • Records of any deviations from standard procedures and protocols such as ingredient substitutions, changes in water and fat content, and other chemical interaction • Details of the calculations • Results of any validation analysis performed on the end product
Ingredients in database	• A precise description of the product, including UPC/code numbers and supplier • Code number in the database • Constituents of the ingredient (and proportions if available) • Source of the nutrient information
Documentation	• Documentation from suppliers, including laboratory analysis if available

V. Data for Nutrition Labelling

A. The Nutrition Facts Table

One way that nutrient data are used for nutrition labelling is in the creation of Nutrition Facts tables (see Figure A).

Nutrition Facts tables must be included on most prepackaged foods, giving consumers information on the nutrient content of those food products. This information, displayed in a standardized format and in the same order, includes Calories and rounded nutrient values for a stated amount of food. Thirteen core nutrients are always part of the declaration; there is also a "closed" list of other nutrients that may be provided. The information must appear in both English and French.

Depending on the nutrient, the value must be expressed either in absolute units of measurement (e.g. grams, milligrams) or as relative amounts (percentage of the reference Daily Value; % DV), or both. Both absolute units and % DVs are subject to rounding rules.

Figure A: Sample Nutrition Facts table

Nutrition Facts / Valeur nutritive
Serving Size (10 g) / Portion (10 g)
Servings Per Container / Portions par contenant

Amount Teneur	% Daily Value % valeur quotidienne
Calories / Calories 50	
Fat / Lipides 4 g	**6** %
Saturated / saturés 2 g + Trans / trans 0 g	**10** %
Cholesterol / Cholestérol 5 mg	**2** %
Sodium / Sodium 5 mg	**0** %
Carbohydrate / Glucides 4 g	**1** %
Fibre / Fibres 0 g	**0** %
Sugars / Sucres 4 g	
Protein / Protéines 1 g	
Vitamin A / Vitamine A	0 %
Vitamin C / Vitamine C	0 %
Calcium / Calcium	2 %
Iron / Fer	2 %

1. Nutrition Facts table: core information, standard format

For information about nutrient definitions, the core information required, additional permitted nutrients, conditions for the inclusion of certain nutrients, units of expression and rounding rules, see the CFIA *2003 Guide to Food Labelling and Advertising*[27] or Sections B.01.401 and B.01.402 of the Food and Drug Regulations.[28]

2. What are Daily Values (DVs)?

Daily Values (DVs) are reference values based on recommendations for a healthy diet. The Daily Value is equivalent to either the **Recommended Daily Intake** (for vitamins and mineral nutrients) or the **Reference Standard** (for other nutrients).

The % Daily Value is a simple benchmark for evaluating the nutrient content of foods quickly and easily. When the nutrient content is expressed as a percentage of Daily Value (% DV), the consumer can see whether there is a lot or a little of a nutrient in the specific amount of food. Note that % DVs are not stated for all nutrients; they are required for fat, total saturated and *trans* fatty acids, sodium, carbohydrates, fibre, Vitamins A and C, calcium and iron. The reference values for computing % DVs can be found in the *2003 Guide to Food Labelling and Advertising*.

3. What must be included in a Nutrition Facts table?

The Nutrition Facts table lists Calories and 13 core nutrients in a consistent order. All of the information in the Nutrition Facts table must be based on a stated serving of food. Regulated reference amounts of food can help in setting a serving size.

Certain other nutrients also may be included (a "closed" list). It becomes mandatory to declare these nutrients if they are added to the food or if they are the subject of a claim.

- Except for vitamins and mineral nutrients, the label indicates the actual amount (quantity) of the nutrient in the stated serving of food. Even if the nutrient amount is zero, it is listed.
- For vitamins and mineral nutrients, the nutrient content is expressed as a percentage of a reference value, the Daily Value. The % DV gives a context to the actual amount of a nutrient.
- For a few nutrients, both the actual amount and % DV are provided.

[27] *2003 Guide to Food Labelling and Advertising*: www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml

[28] Food and Drug Regulations, Sections B.01.401 and B.01.402
www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_b-text-1.pdf

4. Are Canadian and US Nutrition Facts the same?

Although Canadian and US Nutrition Facts tables appear to be similar, it is not appropriate simply to portray the US information in the Canadian format. Canadian values may differ from US values for several reasons:

- optional elements (non-core nutrients) may differ
- rounding rules for nutrient values are not the same
- technical definitions of some nutrients are different
- the reference standards for % DV calculations are not the same for some nutrients

Additional information on the differences between the Canadian and US Nutrition Facts tables can be found in Section 5.17 of the CFIA *2003 Guide to Food Labelling and Advertising*.[29] If you have the original unrounded values underlying a set of US Nutrition Facts, you may be able to use them to calculate Canadian values.

> Only Canadian Nutrition Facts tables (using the specified format in English and in French) are acceptable on products sold in Canada.
>
> Neither US Nutrition Facts tables nor nutrition labelling systems of other countries may be used.

5. Who is responsible for the accuracy of nutrient values on labels?

Regardless of how nutrient values are determined, food manufacturers, importers and distributors are responsible for the accuracy of label values and for maintaining appropriate documentation related to those values. Ingredient suppliers are also accountable for the nutrition information they provide to their customers.

There are particular requirements for a nutrition labelling value. These standards can make treatment of data for this use quite different from other uses:

- There are compliance standards (tests) that describe expected agreement between a nutrient value on a label and what is found in a sample of packages (page 68).
- Presentation of the results on the label must adhere to certain rounding rules.

If you start with sound, valid data for calculating nutrient values, it is more likely that the values you put on the label will meet these standards. No amount of statistical treatment at this stage can rectify weaknesses at the data gathering stage.

[29] CFIA *2003 Guide to Food Labelling and Advertising*, Section 5.17
www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml

- In the case of laboratory analysis (see **Part 2, Chapter III**, page 39), you need to have sufficient samples, samples that are representative of your product or the entirety of the product line, and appropriate laboratory methods. These factors all affect the quality and the confidence you have in the final results.
- When nutrient values are established indirectly (see **Part 2, Chapter IV**, page 54), their quality will depend on the reliability and specificity of the ingredient information, the extent of natural variation and magnitude of processing effects.

Further information on the specific issues related to using these different approaches to generate nutrient labels can be found in **Section F** (page 73).

> It is critical to invest efficiently and sufficiently in the process used to obtain the underlying data.

B. Compliance Expectations for Nutrition Labelling

CFIA conducts compliance tests to assess the accuracy of nutrient values used for nutrition labelling. The CFIA *Nutrition Labelling Compliance Test*[30] provides detailed definitions and guiding principles for compliance expectations. A brief summary of a few key points are provided here, but it is important that the full document be consulted prior to developing values for nutrition labelling. In the compliance test, two different categories of nutrients are described:

Class I: a vitamin or mineral nutrient that is added

Class II: a nutrient, other than an added vitamin or mineral nutrient, that is in the Nutrition Facts table or that is subject to regulations for nutrient content claims or diet-related health claims

Note that these classes pertain to a nutrient. Thus a single food can contain nutrients in either or both classes. For instance, enriched pasta has added vitamins and minerals (Class I) and naturally occurring nutrients such as carbohydrates and protein (Class II).

Briefly, when CFIA performs a compliance test to verify the accuracy of declared values or the truthfulness of claims, it takes at least 12 individual consumer units randomly from a single lot in the future, and combines them to make 3 composites with at least 4 individual consumer units each. The three composites are analyzed separately and the average of the three is used to estimate the nutrient value of the lot. CFIA uses this compliance sample to assess three specific criteria for the expectations between the label values and the marketed product. As well as these three criteria, CFIA also considers whether the look and contents of the Nutrition Facts table and rounding rules are in compliance with regulations. Table 5 on the next page summarizes the three criteria.

Looking specifically at Criterion 2, CFIA outlines different expectations for a label value for nutrients in the different classes:

- Class I nutrients (added vitamins and minerals):
  - The average of a future test of 12 individual units from the same lot must be not less than the label value.
- Class II nutrients (min) nutrients (e.g. protein, carbohydrate, fibre):
  - The average of a future test of 12 individual units from the same lot must be not less than 80% of the label value.
- Class II nutrients (max) nutrients (e.g. Calories, fat, saturated fat, *trans* fat, cholesterol, sugars, naturally occurring vitamins and minerals, sodium):
  - The average of a future test of 12 individual units from the same lot must be no more than 120% of the label value.

These expectations must be considered when you determine the values to use for nutrition labelling.

[30] CFIA *Nutrition Labelling Compliance Test*: www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

Table 5: Sampling Plan and Tolerances

Sample is three composite sub-samples of four consumer units randomly selected from a lot.

Class of Nutrient	Description	Nutrients	Acceptance Criterion 1: Sub-Sample	Acceptance Criterion 2: Tolerances[1,2]	Acceptance Criterion 3: 99% Confidence Interval
Class I (min)[3]	added nutrients (e.g. added Vitamin C)	added vitamins, mineral nutrients, amino acids	each sub-sample ≥ 50% declared nutrient value	≥ declared nutrient value	$\left[\frac{s \times 0.4344}{\bar{x}}\right] \leq 0.1$ [4]
Class II (min)[3]	a naturally occurring nutrient that is declared in the Nutrition Facts table and/or for which a health or nutrient content claim is made	protein, polyunsaturated fatty acids, omega-3 fatty acids, omega-6 fatty acids, monounsaturated fatty acids, carbohydrates, starch, fibre, soluble fibre, insoluble fibre, potassium, vitamins, minerals	each sub-sample ≥ 50% declared nutrient value	≥ 80% declared nutrient value	*does not apply*
Class II (max)[3]	a naturally occurring nutrient that is declared in the Nutrition Facts table and/or for which a health or nutrient content claim is made	calories, fat, saturated fat, *trans* fat, cholesterol, sodium, sugars, sugar alcohols	≤150% declared nutrient value	≤ 120% declared nutrient value	*does not apply*

Notes:

[1] Tolerances are one-sided. Nutrient content may vary within good manufacturing practices, either above declared value, where a minimum is required or below declared value, where a maximum is required and provided there is no risk to health and the label is not misleading.

[2] Tolerances are based on declared nutrient value and applied to pre-round value.

[3] (min) - where minimum level required; (max) - where maximum level required

[4] s = standard deviation; $\bar{x}$ = mean nutrient value

Source: CFIA: *Nutrition Labelling Compliance Test*, Part I, CFIA, 2003

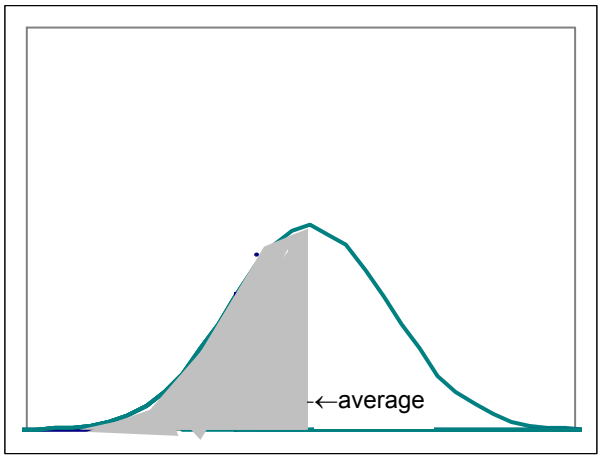
C. Using Means as a Label Value

It is often tempting, after taking care to implement a good sample design and then calculating the appropriate representative average, to use this average for the label value.

- In many cases this will be a suitable value and an acceptable product would have a high probability of passing the compliance test.
- However, in many other instances you may need a more conservative value than the simple average so that an acceptable product is not found erroneously to be out of compliance.

For the Class I nutrients, the compliance test average of 12 units must not be less than the label value. If the distribution of nutrient values is symmetric, then about half of all averages of 12 items chosen in the future from the product line will be below your observed production average, and half will be above (see Figure B). If you chose to label with the observed production average, there is a significant risk that an acceptable lot will fail the compliance test. In this case, it would be better to use a value that is lower than the observed production average as a label value to reduce the chance of failing to comply.

Figure B: Class I Nutrients (Symmetric Distribution)



For the Class II (min) nutrients, the compliance test average of 12 units will be compared with a threshold of 80% of the value declared on the label. If the product has a large amount of variability, then there is a significant chance that an average of 12 units chosen in the future from the product line will be below 80% of your observed production average.

Compare Figures C and D below. These graphs show the distribution of production averages for two products that have the same average value but quite different amounts of variability.

Figure C: Class II (Min) Nutrients — Limited Variation

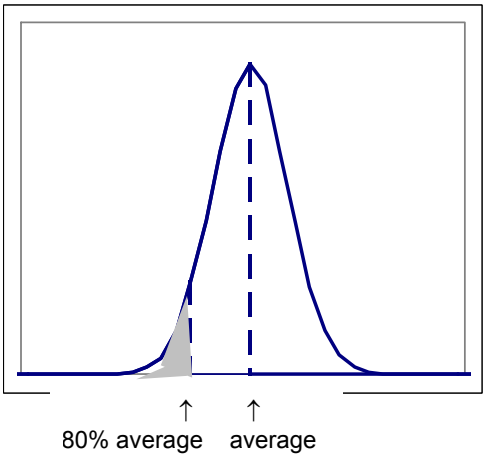
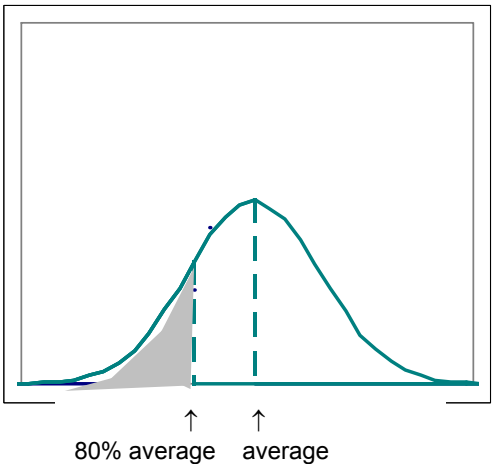


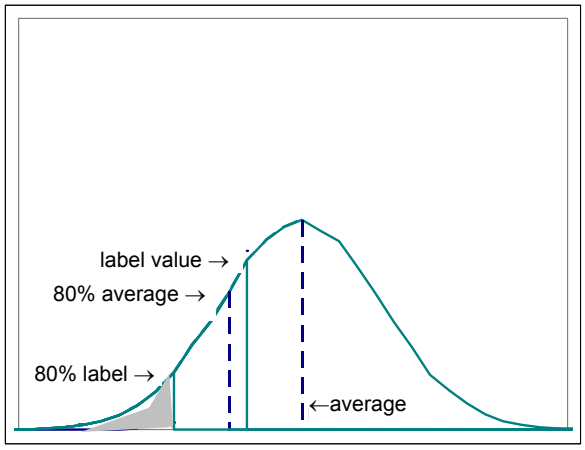
Figure D: Class II (Min) Nutrients — Large Variation



If both products use the average value for the label, then the probability is much higher that the average of a future sample of 12 units of the product line with the greater variability (Figure D) will fall below the threshold. If a slightly lower value were chosen to label this particular product (such as the solid line below the average in Figure E), then 80% of this lower value would be the compliance threshold. As a result, the likelihood of compliance samples falling below the threshold would be reduced.

Therefore, for products with a large amount of variation, you may want to use a conservative value for the label that is lower than the average to reduce the chance of your product failing to comply with the regulations.

Figure E: Class II (Min) Nutrients — Choosing a Conservative Label Value



Conversely, for Class II (max) nutrients, you should consider using a label value that is somewhat higher than the average. Unlike Class I nutrients, assessing the likelihood of compliance failure for Class II nutrients is not always straightforward. The process must take into account a complex combination of factors:

- the underlying variability in the product line (the key factor)
- the sample size used to estimate the lot average and variability
- the degree of certainty the producer wants to have for the prediction of future lot averages

There is no regulated approach to arriving at an alternative label value. It is a decision that is ultimately guided by the risk management approach that the manufacturer or industry chooses with respect to nutrition labelling—the degree of certainty around compliance testing that is desired.

There is, however, an approach that might be used that takes the three factors above into consideration and yields what is often referred to as a *predictive value* as a possible alternative to an average for labels for all three classes of nutrients.

The statistical formulas for determining predictive values can be found in the *FDA Nutrition Labeling Manual.*[31] These formulas may seem complicated, but the underlying concept for calculating predictive values is quite straightforward. The calculation itself can be set up in most spreadsheets. You use what is known about the product, such as the observed production lot average and variability, to estimate the likely behaviour of the average for 12 individual unit samples selected in the future from the product. This specific information is gained most directly from product sampling and laboratory testing.

From this information, and using the formula noted above, a conservative value (derived from the predictive value) for a label can be found. The next step is to compare the calculated conservative value to the mean. There are specific rules, also described in the *FDA Nutrition Labeling Manual*, to help you decide when to choose the mean and when to choose the more conservative value for your product. The choice is made so that when the compliance test is applied, future averages of acceptable product would likely be within the compliance tolerances and would have a high likelihood of passing the compliance test.

To obtain a sound calculated result, you need representative estimates of the average and the variability in the product. This highlights again the importance of an appropriate sample design and sample size at the outset.

[31] *FDA Nutrition Labeling Manual*: www.cfsan.fda.gov/~dms/nutrguid.html

D. Calculating Nutrients per Serving Size

Once you have established whether the average or a more conservative value is to be used for your label, the value needs to be converted to the appropriate portion size for the product. The regulations pertaining to serving sizes and reference amounts can be found in the tables following Section B.01.401 of the Food and Drug Regulations.[32]

This calculation usually consists of converting your results to the number of grams in the appropriate serving. Note that the serving size itself has no impact on whether an average or a more conservative value should be used.

E. Rounding

The final step is to apply the rounding rules to determine how the nutrient value per serving size is to be represented on the label. Rounding is a process whereby a range of numbers is represented by a single number. For example, "nutrient values greater than 4.5 grams and less than 5.5 grams" are to be represented by "5 grams". These ranges of pre-rounded values are taken into account when the compliance test is applied. Specific rounding rules exist for different nutrients and for different levels of nutrients. These rules can be found in the table of core information in the revised Food and Drug Regulations following Sections B.01.401 and B.01.402.[33]

F. Use of Different Approaches to Generate Label Values

The various issues related to using different approaches for establishing nutrient levels have been described in general in **Part 2, Chapters III** and **IV**. Here we consider some specific issues related to generating nutrient labels.

1. Direct approach

Using a product sampling and laboratory analysis approach, the industry or manufacturer can have more direct involvement in determining the nature of the sampling, the accuracy and precision required and the calculation of the results. The answers to the key questions about data quality that allow assessment of the data will be directly at hand or readily available from the laboratory hired to conduct sampling and analysis. You will know that the results are specific to your finished product and take into account your ingredients, your processing, and your current product. This will provide greater confidence that the results are representative of the actual nutrient values in your product.

The raw laboratory results should be available and the steps for the calculations documented. This will give you the flexibility to assess variability and to determine whether you need to use a predictive value for the label (see page 72). With the raw data as a starting point, you

[32] See the tables following the Food and Drug Regulations Section B.01.401
www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_b-text-1.pdf

[33] See the table of core information following the Food and Drug Regulations Sections B.01.401 and B.01.402
www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_b-text-1.pdf

will have control over when and how rounding is applied in the data treatment process. This complete transparency will provide greater confidence in the nature of the data treatment. All of the pieces will be available to allow for informed decisions related directly to your specific risk management approach.

Sampling and laboratory analysis also provide a firm baseline for potential future labels when minor product modifications have been made; you may not need to conduct a whole new cycle of sampling and testing.

2. Indirect approach

When databases and other existing sources of information on nutrient values are used, transparency and control over the collection of data and the derivation of results involved is reduced compared with the direct sampling and laboratory analysis approach. It can be more difficult to get comprehensive answers to the questions about data quality. Combining the results from a database may require further adjustment to take into account the impacts of processing; some verification of this adjustment would provide greater confidence that the data reflect your finished product appropriately. It may not be clear where and how rounding of values in the ingredient database has taken place unless this information has been specified. It can be difficult to assess the impact of any rounding on the label value to choose.

Assessing the variability present in the finished product is difficult from the information in ingredient databases. Calculating predictive values (as described on page 72) is not possible technically from ingredient databases. This makes it difficult to make an informed decision about the label value to use that would be compatible with your risk management approach. Again, validation by laboratory analysis would help provide insight into how well the database calculation represents the nutrient values for your product.

If you use ingredient composition databases, you will need procedures to ensure that the nutrient values are used only for specific applications. For example, you should have a procedure to ensure that nutrient data specific for one product formulation or process are not used to prepare nutrient declarations for similar product formulations or processes, without assurance that the data are applicable to those products or processes. You should also have procedures to ensure that the nutrient values receive reviews, audits, and validation through nutrient analysis as often as necessary.

APPENDICES

Appendix A: Glossary of Terms and Acronyms

The terminology related to product sampling used in this Guide is similar to that found in the CFIA *Nutrition Labelling Compliance Test*.[1] There can be significant confusion in discussions about product sampling due to the language and vocabulary used. This confusion arises in part from the different definitions used by different organizations and individuals (for example, there are definitions provided by standards organizations, international organizations, and quality assurance groups). For the most part, you need to consider the important distinctions intended by these definitions rather than the specifics of the definitions themselves. When examining any document describing sampling procedures, it is worthwhile to confirm the definitions intended.

Glossary of Terms

Term	Definition Used in this Guide
accuracy	• The closeness of agreement between a test result and the accepted reference value.
Atwater factors	• The factors developed by W.O. Atwater to calculate the energy contributed by protein, fat, and carbohydrates to foods.
average or *mean*	• A measure of a typical value for a large number of *product units*, often calculated using the familiar total of the values divided by the number of values.
database	• A collection of data brought together and stored in some manner for future retrieval. It could be as simple as a file folder containing information on each ingredient, or as complex as a set of relational electronic files. A database can contain ingredient-specific data, generic data, or a combination of both. There are several types of databases, including databases that are company-specific, government reference databases, and commercial databases.
calculated or treated values	• Nutrient values computed or estimated by mathematical adjustment. Normalizing nutrients to an average moisture or fat value, use of retention factors, and substitution of similar ingredients in a formulation or recipe are examples of calculated values.
commingling	• Units capturing different factors (such as from different breeds, over different factories or over different lots) are mixed; the resulting laboratory analysis reflects an average over the different factors. The information on the nature and magnitude of nutrient differences due to these factors is lost.
compliance test	• A test conducted by CFIA for verifying the accuracy of nutrient values on labels and in advertising via laboratory analysis as part of assessing compliance with the Food and Drug Regulations.
compositing	• Units that were produced under similar conditions (such as within an orchard, from the same herding region or from the same production lot) are mixed. The mixing of "like" units preserves the information about the factors that make the nutrient values vary.
design effect	• The impact of the type of sample design chosen on the number of samples needed to estimate a mean with a given precision and certainty.

[1] CFIA *Nutrition Labelling Compliance Test*, Appendix 2 – Statistical Framework, Part C: Glossary
www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

Term	Definition Used in this Guide
formulation	• The estimated proportion by weight of ingredients in a multi-ingredient commercial food item when other characteristics of the food item are known or can be set. Characteristics which may be known or can be set include: order of predominance of ingredients, retention codes, target moisture level of individual ingredients and final product, and lower and upper bounds on the proportion of any individual ingredient. As a minimum, to derive a formulation, some nutrient values must be known and flagged for matching.
imputed	• Nutrient values developed when analytical values are unavailable. Nutrient values from another form of the same food, or another species of the same genus are examples of imputed values.
item *unit* (or *individual unit*)	• An identifiable element of the finished product or food, usually in the form or package potentially provided to a consumer. • It may be a raw, single-ingredient food, such as carrots, or a manufactured product. • The unit does not necessarily match the usual portion or serving size. The units defined must not overlap, and taken together must account for every element in that product line. • Sometimes the unit may be obvious (e.g. single eggs in an egg production, or boxes of ready-to-eat cereal for a cereal manufacturer); while at other times there may be a choice of how to determine a unit (e.g. a quantity of sugar from a bulk shipment). • At times the finished units from one producer (e.g. sugar) may be an ingredient for another producer to form quite a different end product unit (e.g. chocolate bar).
lot (or *batch*)	• A collection of identically labelled units produced under conditions as nearly uniform as possible. • Note that for nutrition labelling, there are some additional descriptors for "lots".[2]
manufacturer	• In this document the term *manufacturer* in most instances refers collectively to producers, manufacturers, processors, importers, distributors and suppliers of food products and ingredients.
median	• A measure of a typical value; the mid-point in the set of values that are being considered, once the values have been arranged in order of size.
outliers	• Unusually large or small values.
pilot	• A small representative study. Useful in helping to determine the factors that need to be considered in sampling, such as the amount of variability in the product line overall. This may involve collecting a limited number of units in a structured way, followed by laboratory analysis.
pooling	• Individual product units are grouped into a number of pooled units, and laboratory tests are conducted on the pooled groups. When units are pooled for laboratory analysis, each resulting nutrient value reflects the average of the units that went into the pooling. • *Compositing* and *commingling* are two terms often used to describe different ways to pool units.
precision	• The ability of a measurement to be consistently reproduced.

[2] CFIA *Nutrition Labelling Compliance Test*, Appendix 2 – Statistical Framework, Part C: Glossary
www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

Term	Definition Used in this Guide
predictive values	• Nutrient values determined using statistical formulas that estimate the likely behaviour of future averages; can be used as an alternative to average values for labelling purposes.
probability sampling	• Every unit has a chance to be selected, and this chance can be calculated. Probability sampling, properly implemented, will allow appropriate treatment of the resulting data to provide representative estimates, and will allow estimation of the degree of certainty for that estimate.
proximate components	• Fat, protein, carbohydrates, ash and moisture content, determined by prescribed methods.
raw data	• Original data that have not been treated (on which no calculations have been performed).
raw, single-ingredient food	• Examples include fresh vegetables and fruit, cuts of meat, fish, eggs.
recipe	• The known weight or measure of ingredients in a multi-ingredient food item. Amounts of ingredients may be expressed in household volume measure units such as cups and tablespoons or may be expressed as gram weights. The term *recipe* is generally applied to a food item prepared from component ingredients in a household or institutional setting. The term may also apply to a commercial multi-ingredient food item for which the amounts of ingredients are set, rather than estimated.
sample	• This term can be used in two different ways depending on the context, which can lead to confusion. • On the one hand, a *sample* is a collection of individual units or items. There should be an accompanying plan called a *sampling plan* or *sample design* that explains how this number of units was collected from different lots or parts of the entire product line. • However, it is also common to see the term *sample* used to refer to a part of the individual unit that undergoes laboratory tests, sometimes also called a *test sample*. • In this document, *sample* is used to describe a collection of a number of individual units or items.
sample frame	• The complete population of product units to which the nutrient values are to pertain and from which the sample will be chosen.
standard deviation	• A measure of variability (spread); the square root of the variance.
standard error of the mean	• An estimate of variability (spread); the standard deviation expected in the set of means from repeated random samples of a specific sample size.
variability or *variance*	• The spread, range, or dispersion of the values.
yield	• The weight of the prepared item divided by the weight of the unprepared item. Yield is affected by such factors as moisture loss.

Acronyms Used in this Guide

Acronym	Meaning
AOAC INTERNATIONAL	AOAC is no longer used as an acronym; AOAC INTERNATIONAL is the legal name An independent association of analytical communities which published a reference of methods used in analyzing the composition of foods.
CAN-P-4D	Canadian Procedural Document 4D CAN-P documents provide the Canadian public with the policies, procedures and criteria of the Standards Council of Canada for activities such as accreditation and international standardization.
CFIA	Canadian Food Inspection Agency CFIA is the federal agency that delivers all inspection services related to food; animal health; and plant protection. CFIA is responsible for enforcing the food requirements of the Food and Drugs Act and the Food and Drug Regulations.
CNF	Canadian Nutrient File A computerized, bilingual generic food composition database containing average values for nutrients in foods available in Canada.
DFE	Dietary Folate Equivalents
DRI	Dietary Reference Intake
DV	Daily Value A reference value based on recommendations for a healthy diet; appears in the Nutrition Facts table.
% DV	Percent Daily Value A simple benchmark for evaluating the nutrient content of foods quickly and easily; appears in the Nutrition Facts table.
FDA	Food and Drug Administration, US Department of Health and Human Services
ISO	International Organization for Standardization
IU	International Units
PALCAN	Program for the Accreditation of Laboratories/Canada PALCAN is the Standards Council of Canada's internationally recognized laboratory accreditation program.
RAE	Retinol Activity Equivalents
SCC	Standards Council of Canada SCC accredits the organizations that develop standards and that verify the conformity of products or services to standards.
RE	Retinol Equivalents
TDF	Total Dietary Fibre
UPC	Universal Product Code
USDA	United States Department of Agriculture
USDA-SR	USDA National Nutrient Database for Standard Reference A generic reference database on food composition maintained by the USDA Agricultural Research Service.

Appendix B: Technical Definitions of Certain Nutrients

Many nutrients can have various chemical forms, each with a different contribution to the biological activity (physiological effectiveness).

A. Vitamin A

The primary unit of biological activity for Vitamin A is called all-*trans* retinol. Carotenoids are a group of plant pigments that are provitamins (precursors) to Vitamin A. The body cannot use these inactive forms until it converts them to the active form, which is retinol. Thus, the total Vitamin A activity of a food is expressed as a sum of its retinol content plus the amount of retinol expected to be produced when the body converts the carotenoid content to retinol.

Unfortunately, more than one method of expressing this total activity has been developed and no method is used universally. Recently, the National Academy of Sciences determined that the contribution from carotenoids is roughly half of that thought previously and as a result has suggested a new unit, Retinol Activity Equivalents.[1]

- Nutrition labels in the US use International Units (IU):
  1 IU = 0.3 µg retinol
  1 IU = 0.6 µg beta-carotene
  1 IU = 1.2 µg other carotenoids
- Vitamin A in the Canadian Nutrition Facts table is expressed in Retinol Equivalents (RE):
  1 RE = 1µg retinol + (µg beta-carotene/6) + (µg other carotenoids/12)
- The new Dietary Reference Intake (DRI) recommendations[1] suggest that Vitamin A should be expressed in terms of Retinol Activity Equivalents (RAE):
  1 RAE = 1µg retinol + (µg beta-carotene/12) + (µg other carotenoids/24)

It is not simple or advisable to convert between REs and IUs in a food containing both retinol and carotenoids because you do not have information on the proportions of each. Calculating any of these activity standards is best done by starting with the amounts, in µg, of each fraction contributing to retinol activity.

[1] The corresponding DRI report can be accessed via www.nap.edu/catalog/10026.html

B. Folate

Foods can contain two chemical forms that contribute to folate bioactivity. These are the naturally occurring or food folate and the added synthetic form, folic acid. Folic acid is more active than food folate.

As a result you may see any of the following in sources of nutrient data:

- Food folate, also called naturally occurring folate, in µg
- Folic acid, synthetic, in µg
- The arithmetic sum of food folate and folic acid (not accounting for activity), sometimes referred to as total folacin or simply as folate, in µg. This is still the unit to be used on the Canadian label.
- Dietary Folate Equivalents

  1 DFE = (µg folic acid x 1.7) + µg food folate

  The DFE, which accounts for the difference in bioactivity between the naturally occurring and synthetic forms, is now the most common unit of expression when referring to recent population nutrition studies.

C. Vitamin D

Sometimes this nutrient is reported in µg Vitamin D; other times in International Units (IU):

1 IU = 40 x µg Vitamin D

D. Vitamin E

There are a number of different forms (isomers) of Vitamin E. In the past a calculation of Vitamin E equivalents that took into account activities of various isomers was most commonly used. However, the National Academy of Sciences now has determined that the only isomer of significant activity is RR-alpha-tocopherol, expressed in µg.[2]

E. Total Dietary Fibre

There are four methods of analysis for Total Dietary Fibre (TDF) approved by CFIA. The results can differ slightly in certain foods. Regardless of your source (laboratory, database, supplier), you need to be sure that the method of analysis is appropriate for your application. For example, the definitions of TDF for labelling purposes differ between the US and Canada. This sometimes can result in limitations on what can be included in the fibre value, particularly when considering novel foods.

[2] The corresponding DRI report can be accessed via www.nap.edu/catalog/9810.html

Appendix C: Choosing a Consultant

It is important for you to understand the underlying issues related to generating nutrient values. Yet you may find instances when you need to hire a consultant on a number of issues, as highlighted in this document. Consultants offer a range of services which include determining the best approach for your application, planning the sampling and analysis, using a database for calculations and deriving Nutrition Facts tables.

The specialization of food composition is a relatively new field, particularly in this technologically advanced and scientifically sophisticated era. International standards, application to risk assessment studies and compliance testing of label values are all pressures demanding greater attention to data accuracy, information regarding variance, and documentation of data sources and quality.

At the same time as the application of nutrient data has become a more complex science, technology can hide much of the detail behind powerful software programs. As a result the use of this software can appear misleadingly easy for the unwary. In the past, it was not uncommon even for those with professional designations in food science or dietetics to produce recipe information, menus, or labels from inappropriate data sources with no allowance for variance, statistics or potential for nutrient losses. There is reason then for caution to ensure you choose a consultant in whom you can have confidence.

You may be able to get help identifying suitable consultants or statisticians by contacting a marketing board, professional association or industry association.

Some questions you would be wise to ask an individual or company providing these services are included in the following contract checklist.

Checklist for Choosing a Consultant

Factors	Questions to Ask
Experience	• How many years have they been in business and how many years of experience do they have in nutrient analysis? • Does the scope of their expertise meet your needs for sample design, analysis, calculation and verification?
Needs assessment	• Are they able to conduct a needs assessment for your product line and your intended use? Are they familiar with: - Your product line and the specific nutrients of concern? - Suitable approaches for your application? - Designing sample plans? - Choosing a laboratory, nutrient databases and/or nutrient analysis software programs?
Databases/software	• Do they use a commercially available nutrient analysis database/software, their own in-house nutrient database/software system, or a combination of both? • Which commercially developed databases/software are they using? What other types of nutrient data sources might they use? • What are the criteria for confidence in the quality and suitability of the data for the purpose you intend?
Source accuracy	• Are the nutrient data sources they use cross-checked for accuracy? • Or do they personally cross-check nutrient data? If so, what parameters do they use?
Yield factors	• Do they apply nutrient yield factors when necessary in their analysis work owing to weight losses? If so, how do they obtain information for these yield factors?
Missing values	• How do they manage when a value (such as *trans* fat) is required but is not present in any validated data source?
Laboratory used	• What standards do they require a laboratory to follow for the nutrient analysis work performed? How did they choose those standards? (see also **Appendix D**) • Do they work in affiliation with a specific laboratory? If so, which laboratory, and why?
Data treatment	• What do they know about the appropriate calculations and data manipulations to obtain the values needed?

Appendix D: Choosing a Laboratory

Choosing a competent laboratory is very important to ensure the accuracy of your nutrient values. The laboratory you choose should be able to demonstrate experience in analysis involving food matrices; it is not enough for them to have experience analyzing blood or water because food is much more complex than either of those substances. The laboratory should also have experience in analysis of the nutrients of interest in your particular food matrix. As with any consultant you would hire, you should review the qualifications of the laboratory carefully.

Some of the important considerations when deciding whether to establish a business relationship with a laboratory are listed in the contract checklist on the next page.

Checklist for Choosing a Laboratory

Factors	Demonstrated Expertise or Issues to Consider	Questions to Ask
Experience	Analysis involving food matrices	• Who is their accrediting body? Are they accredited to CAN-P-4D standards? • Do they have appropriate equipment for homogenizing and/or cooking? • Do they have dissection experience?
	Analysis of nutrients in food	• Which nutrients are they accredited to analyze? • Do they use an AOAC-approved, CFIA-recommended method for each nutrient? • Do they provide details of those methods to you?
Quality control	Analytical quality control results performed during the relevant period	• How do they handle: - Calibration of equipment - Change in staff - Recoveries - Reference material results - Replicates - Blind samples
Treatment of samples	Collection protocol (optional)	• Who is responsible for the sample design? • What are the justifications for the design chosen? • Who is collecting and transporting the samples? • Are samples transported in a manner to retain integrity?
	Capacity of the laboratory	• How many units can be processed in what timeframe? • Is scheduling of the samples a concern? • Do they have adequate storage facilities?
Location	Transportation of samples (shipping time and costs)	• What are the expected shipping time and costs?
Costs	Cost savings owing to efficiencies or owing to use of calculations are reflected in the price	• Is there one price for analysis of nutrients that can be analyzed simultaneously? Examples: - Total fat (as triglyceride equivalents), saturated fatty acids and *trans* fatty acids - Calcium and Iron • Is the price minimal for nutrients that are determined by calculation, not by chemical analysis? Examples: - Energy - Carbohydrates
Other	Publication rights	• How will the confidentiality of the data be ensured?
	Report formats	• Will they include all of the raw data in their report?

Appendix E: Accounting for Effects of Processing

Sometimes you may need to calculate nutrient values from data on your specific ingredients for an end product that is cooked or otherwise processed. In those cases, you need to account for changes in the nutrients that occur during these processes. The most common changes are loss or gain of moisture, loss or gain of fat and/or loss of vitamin or mineral activity.

A. Moisture

Changes in moisture, or water content, can significantly affect nutrient content per unit of weight. For example, baking will result in evaporation and loss of moisture, thus concentrating the amounts of the other nutrients. The nutrient content per unit of weight will be increased in the baked item. Conversely, cooking pasta will always dilute the nutrient density compared with the raw material. The extent of this dilution will vary because the water content of cooked pasta varies, depending on how long it has been cooked and how much evaporation has occurred post-cooking.

B. Fat

Many different processing methods will cause loss or gain of fat. Broiling will cause fat to drip from the product and result in lower fat values than you would obtain by simply summing the values in the raw ingredients. Deep frying will cause a gain in fat from the frying oil, and it will be a different type of fat than the fat in the original product.

C. Vitamins and Minerals

Processing may have a significant impact on the amount of vitamins or minerals in your product. The *USDA Table of Nutrient Retention Factors, Release 5* (2003)[1] is a good source of information on retention of vitamins and minerals in processed foods. Applying these factors to the amounts of vitamins and minerals in raw ingredients generates approximate amounts that are likely to be remaining after processing. Although these are generic factors they are a good starting point.

As an example, the published tables will list a process such as:

Milk, heated, approximately 1 hour *Vitamin C, 45%*

This means that 45% of the activity of Vitamin C is retained after this process. You would need to multiply the Vitamin C value in your raw milk by a factor of 0.45 to obtain the amount of Vitamin C expected to remain in the milk after 1 hour of heating. Each ingredient in your formulation may have different retention factors for each vitamin or mineral.

However, on the basis of validation tests in the laboratory you may find that for some ingredients or in certain types of mixtures, one or more factors needs to be adjusted upward or downward to reflect actual nutrient amounts remaining after processing. In addition, if your

[1] *USDA Table of Nutrient Retention Factors*: www.nal.usda.gov/fnic/foodcomp/Data/index.html#retention

processes are unique and not listed in the USDA tables, you will need to obtain the retention factors through your own analysis of starting ingredients and end product.

D. Calculation of Product Values

Examples of the effects of processing on the water, fat, carbohydrate and protein contents of three products are presented below. These examples demonstrate the varying complexity of the effects of processing, from negligible in the case of a dry cake mix, to more complex situations for doughnuts and pre-cooked beef patties.

1. Dry cake mix

As illustrated in the chart on the next page, when dry ingredients are simply combined and not further processed the calculation is straightforward and nutrient adjustments are not required.

2. Doughnut

The nutrients for the raw weight of the doughnut can be established easily. If the finished weight is known, the net weight change can be determined easily; however, you cannot calculate the nutrient amounts without knowing how much of this change is attributable to water loss and how much to absorbed frying oil. The water content of the finished doughnut or the amount of oil absorbed must be known.

The finished doughnuts could be sent for laboratory analysis of moisture content only. Or a frying test in which a known weight of raw doughnuts is fried in a known weight of oil could be performed; when frying is complete the oil is again weighed and the amount absorbed can be calculated. However, it is important to remember that fat absorption (and moisture loss) in the frying test may not be identical to those in large-scale production.

3. Pre-cooked beef patty

The nutrient values for the raw patty can be established in a similar manner to the doughnut example. The weight of the cooked patty can be determined, but like the doughnut, the proportions of the weight loss attributable to fat and to water are unknown. Initially it would be beneficial to send this product for laboratory analysis. Over time it may be possible to develop calculation procedures to reliably represent the cooked patty. These calculation procedures in turn could be used as the basis for calculating different varieties of the product with minor ingredient variations.

Contrary to popular belief, cholesterol in meat is associated primarily with the lean portion and usually does not decrease in the same proportion as the fat that is rendered from the meat. Reference databases can assist in developing cooked equivalent cholesterol values for ingredient databases. For example, a comparison of values for raw ground lean beef from the CNF with those for their equivalent cooked weights indicates that approximately 14% of the cholesterol is lost when fat is drained off (compared with approximately 30% fat loss). If drippings are incorporated into the product, however, no cholesterol loss should occur.

Examples of the Effects of Processing

Product	**Main Ingredients**	**Processing Applied**	**Changes in Nutrient Content** (Water, Fat, Carbohydrate and Protein)			
			Significant losses	Significant gains	Minor losses	Little or no loss
Dry Cake Mix	Sugar, flour, baking powder, salt, flavouring	Dry ingredients combined and packaged	None	None	None	—
Doughnut	Whole egg, butter, 2% milk, sugar flour, baking powder, salt, flavouring	Dough prepared, formed and deep fried	Water	Frying fat	None	Carbohydrate and protein
Pre-Cooked Beef Patty	Ground beef (25% fat), dry bread crumbs, chopped carrot, raw onion, whole egg, salt	Ingredients combined, formed and baked, and fat drained off	Water and fat (some absorbed by crumbs)	None	Small amount of protein in drippings	—

The cake mix is clearly the least complicated product for which to calculate nutrient losses. If you manufacture baked goods such as a cake, you will need to examine the retention factors for a variety of vitamins and minerals such as thiamin, riboflavin and niacin. For the doughnuts and beef patties, vitamin and mineral changes can be accounted for by using database ingredients in which these nutrients have been modified during processing; however, determination of water and fat remain a challenge.

Appendix F: Nutrient Data Gaps in Reference Databases

The CNF and the USDA-SR are frequently used reference databases. Both can be useful if care is taken to use them correctly. They are not identical and each has its own strengths and weaknesses. The chart below outlines what each database contains as well as what the Canadian nutrition labelling regulations require.

Nutrient Data in the CNF and USDA-SR Reference Databases

Nutrient	What the CNF contains	What the USDA-SR contains	What Canadian labelling regulations require
Total fat	Total lipid including phospholids and sterols	Total lipid including phospholids, sterols, and so on	Total fatty acids expressed as triglyceride equivalents
All of the unsaturated fatty acids	Both *cis* and *trans* forms, except for margarines and shortenings	Both *cis* and *trans* forms for all foods	Only *cis* forms
Trans fatty acids	Very little data, not supplier specific, high variation	Very little data, very different from Canadian foods	All *trans* fatty acids except conjugated polyunsaturated fatty acids
Omega fatty acids	Many missing records	Many missing records for fatty acid components	Not mandatory, but defined in the regulations if used
Energy	Calculated using specific Atwater factors	Calculated using specific Atwater factors	Calculated using either general Atwater factors (4, 9, 4) or specific Atwater factors
Vitamin A	RAE	RAE and IU	RE
Total sugar	Many missing records	Many missing records	All monosaccharides and disaccharides
Protein	Uses 6.25 as a general conversion factor from nitrogen to protein for most foods. (Exceptions: chocolate, cocoa products, coffee, mushrooms, yeast, soybeans)	Uses 6.25 as a general conversion factor from nitrogen to protein for most foods. (Exceptions: chocolate, cocoa products, coffee, mushrooms, yeast, soybeans)	Uses 6.25
Total Dietary Fibre (TDF)	TDF values reported may have been measured by the Prosky or Mongeau methods of analysis	TDF values reported are all analyzed by variants of the Prosky method of analysis	Reported value should only include approved sources of dietary fibre
All	Has metric conversions	Does not have metric conversions	Metric values

Appendix G: Reviewing Results of Laboratory Analysis

The laboratory analysis should be presented in a complete report, which includes unrounded values along with details of the sample tested and the methods used.

Every sampled unit should be accounted for in the report or results, whether with an individual result or as part of a composite. When describing the product, some details are only relevant to certain types of food products. You need to verify that the details you require for your application have been provided. For example, if the analysis is for a nationally representative food, the critical food description information may be different than that needed for a prepackaged food for labelling purposes. Thus, if your purpose is to include the values in a generic database, you will probably use a mean of values to represent a number of different products. However, if you are planning to create a Nutrition Facts table, the values will represent a single brand of product and will be rounded according to the Food and Drug Regulations.

You can use the checklist on the next page to guide your systematic review of nutrient values and results of calculations reported by the laboratory.

Checklist for Reviewing the Results of Laboratory Analysis

Content	Issue	Details
Unit treatment	Detailed food description	Name, source of units, state of processing, brand name, lot number, date of origin, weight of edible portion, weight of refuse components (if any)
		Dates, storage times and conditions, name of technician(s) for all steps
	Compositing information	Were sample units analyzed separately or were composites formed? If composites were formed, which units went into which composites?
Analysis	Method reference for each nutrient	AOAC-approved, CFIA-recommended, any deviations
	Are all of the nutrients requested included?	Moisture and ash should be included
	Any quality control results	You may or may not want to see these (e.g. recoveries, calibration, reference material results)
Results should include:	All raw, untreated nutrient data for each unit or unit composite	Value per 100 g, units, measurement units (including outliers)
	For nutrients that are expressed eventually as an equivalent, the raw data components contributing the equivalent activity	e.g. for Vitamin A both the μg retinol and μg beta-carotene are provided in addition to the calculated RAE or RE (see **Appendix B**)
	The number of sample units or composites	Were the composites formed as requested and are all sample units accounted for in the results?
	Which values are obtained by laboratory analysis and which by calculation	For example, energy and carbohydrates are often determined by calculation.
	The calculated mean of samples or composites per 100 g and per serving size if desired	Confirm that the correct serving size is used for the calculations.
	Standard deviation or error	Which one is provided? What calculation (formula) was used?
	Factors used for calculations	For example: -nitrogen to protein -calorie calculations
Are there:	Missing values, zeros, or values that are below detectable limits?	Are there any? What explanation is provided? Are any of these significant in your product?
	Unusually large or small values?	Do the results make sense – are they plausible? -Could use the reference database or similar products as a rough guide. -Perform some basic verification as described in **Section A** of this Appendix.
	Rounded values?	Has some rounding already occurred (do the values end in 0, 2 or 5)?
Report format	Electronic is preferable	Some laboratories have automated systems that print results directly to reports. This avoids transcription errors, but may mean that you lose some of the raw data (see above) that it is advisable for you to have.

A. Verifying Laboratory Values

It is important to verify that the laboratory values are correct, as errors can occur during transcription of data and while performing calculations. There are several checks that are fairly easy to perform. Two of these are to check the proximate components, and to verify the energy calculation. An example of each is given here, based on the sample results below.

Sample Results of Laboratory Analysis

Nutrient	Laboratory Values	
	Per 40 g serving	Per 100 g
Ash (g)	0.796	1.99
Calories (kcal)	100.8	252
Calories from Fat (kcal)	2.8	7
Carbohydrates (g)	20.38	50.94
Dietary Fibre (g)	1.25	3.12
Fat (g)	0.33	0.83
Trans fatty acids (g)	0	0.0
Saturated Fatty acids (g)	0.08	0.2
Moisture (g)	14.37	35.93
Protein (g)	4.12	10.31
Sugars (g)	1.52	3.8
Vitamin A (RE):		
Beta-carotene	ND	ND
Retinol	ND	ND
Total Vitamin A	ND	ND
Vitamin C (mg)	ND	ND
Cholesterol (mg)	0.2	0.5
Minerals:		
Sodium (mg)	208	519
Calcium (mg)	52	129
Iron (mg)	1.96	4.89

ND = Not detectable

1. Check proximate components

Check that the proximate components (water, ash, fat, carbohydrate, protein) when expressed in terms of per 100 grams of the sample, add up to 100 (within 5%).

Based on the sample on the previous page, you would sum the values for water, ash, total fat, protein and carbohydrates. This total as shown in the chart to the right should be 100.00 (between 95 and 105).

Weight Check	
Nutrients	Weight (g)
Water	35.93
Ash	1.99
Fat (total)	0.83
Protein	10.31
Carbohydrate	50.94
Total	100.00

2. Verify the energy calculation

The next step is to verify the energy calculation by using general Atwater factors of 4, 9, 4 and 7 kilocalories per gram as follows:

Energy in kcal = (4 x g protein) + (9 x g fat) + (4 x g carbohydrate) + (7 x g alcohol)

In the table below, you can see that good correlation exists between the value obtained by laboratory analysis and the calculated value for our hypothetical product.

	Laboratory analysis		Calculated value
Nutrients	Measured value	Factor (kcal/g)	
Fat (total)	0.83	9	7.47
Protein	10.31	4	41.24
Carbohydrate	50.94	4	203.76
Alcohol	0	7	0
Total Calories		**252**	**252.47**

Keep in mind that many databases and some labels will use specific Atwater factors in the energy calculation, which can differ somewhat from the general Atwater factors demonstrated in this example. In addition, you may need to use specific factors for such nutrients as sugar alcohols.

B. Significance of Outliers

Unusually large or small values (*outliers*) can be very informative and should be reviewed with the laboratory and those who selected the sample. They may actually reflect true variation in the product or result from outside influences.

Some typical causes of outliers are transcription or calculation errors; extraordinary events during collection, transportation, storage, composite formation and analysis; problems in a particular plant (e.g. incomplete mixing of product); and problems with an ingredient from a particular source.

Like missing values, unusual results should not be ignored and only should be removed from a data set if you are certain they do not reflect true variation in the product.

Appendix H: Critical Features of Databases and Software

The following table lists some important features to look for when choosing databases to store nutrient data and software to manipulate the data. A second table on the next page suggests some other useful features.

Critical Features of Databases and Software

Critical Features	Options Available	Optimal Conditions
Original source of the data is defined, and source is reputable.	Suppliers; other labels; CNF; USDA-SR; other	Analyzed supplier data according to quality guidelines described in **Chapter III**
Data are recent.	Date of submission to the software programmer; date of entry into the database; date of entry into the original source database	Date of entry into the original source database
Knowledgeable personnel review data.		
Analytical data are used.	Analytical data; calculated; imputed; averages only	Analytical data according to quality guidelines described in **Chapter III**, with standard deviations
Contains all mandatory nutrients plus others of interest for claims.		Mandatory nutrients plus moisture, ash and any other nutrients you want to add voluntarily to the label
There are no missing records for mandatory nutrients. Zeros are not used when a record is missing.	No missing records; missing records flagged; missing records estimated	Comprehensive datasets for all of the mandatory nutrients, moisture and ash
Metric conversions are available. Reference Amounts are provided as per Canadian regulations.	Imperial (US databases and software programs); metric; metric reference amounts; no conversion factors	Reference amounts and gram weight conversion to the Reference Amounts
User can add foods to database and/or build entirely separate database.	Some programs permit users to choose which databases are accessible at a given time	
Program able to handle high nutrient variation appropriately.	Standard deviations additive; standard deviations used to treat ingredient data before calculations; no indicators of variation	Flexibility, with a number of choices
Provision is made for moisture and fat changes. Provides standard recipes with established moisture and fat loss figures that can be a reference point (rough guide).	Able to do this within the program; possible to do this manually but not always within the program	Program can automatically apply losses and gains of moisture and fat, either entered by user within the program or borrowed from similar standard recipe
Retention factors are considered. The source of the retention factors should be noted.	Retention factors	Automatically accounts for retention factors for the vitamins and minerals, with ability to add additional factors for unique processes
Program can round nutrients as required for labelling after end product calculations.		Programmed with current Canadian Nutrition Facts rounding rules and Daily Values. Can choose whether to work with rounded or unrounded values.
User can select how nutrients are expressed.		Able to select the correct units (e.g. RE units for Vitamin A)

Other Positive Features to Look for in Databases and Software

Feature	Notes
Permits addition of nutrient fields.	You will be able to add voluntary nutrients.
User can include notes pertaining to items added to database.	Allows documentation of data sources and other information within the database.
Added database items are protected from overwriting when software and/or its associated database are updated.	
User can duplicate an existing database item and save it with a new name.	This feature is especially useful when adding copies of ingredients in which some of the nutrients have been modified to reflect processing.
Ingredient name field is large enough to permit meaningful descriptions.	Food naming conventions and abbreviations should be established at the outset.
Software vendor's database is supplemented with other manufacturer's ingredients.	Useful for comparison with ingredient suppliers' information.
User can insert notes in product calculations.	For example, it can be useful for noting manufacturing process and revisions to formulas.
Data can be exported easily to spreadsheet program.	Facilitates supplementary calculations and preparation of custom reports.

REFERENCES

AOAC INTERNATIONAL: *Official Methods of Analysis of AOAC INTERNATIONAL*, 18th Edition Revision 1, 2006
https://my.aoac.org/source/Orders/index.cfm?section=unknown&activesection=Orders

Canadian Food Inspection Agency: *Nutrition Labelling Compliance Test—Nutrition Labelling, Nutrient Content Claims and Health Claims: CFIA Compliance Test to Assess the Accuracy of Nutrient Values*, 2003
www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

Ibid: *2003 Guide to Food Labelling and Advertising*, Draft Document. Fair Labelling Practices Program, Bureau of Food Safety and Consumer Protection, December 2003
www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml

Health Canada: *Canadian Nutrient File*, Food Program, 2005
www.healthcanada.ca/cnf

Note: If you click on "Search online for foods…" that page also includes links to:

- USDA National Nutrient Database for Standard Reference, Release 17
- Nutrient Value of Some Common Foods
- International food composition tables
- Nutrition Labelling - Regulations
- Nutrition Labelling - Compliance testing
- Food and Drug Act and Regulations

Ibid: *Food and Drugs Act* and *Food and Drug Regulations*
www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/e_index.html

Ibid: *Nutrient Value of Some Common Foods*. Health Protection Branch in cooperation with Health Promotion and Programs Branch, 1999 (reprinted 2002)
www.hc-sc.gc.ca/food-aliment/ns-sc/nr-rn/surveillance/e_nutrient_value_of_some_common_.html

Ibid: Nutrition Labelling Regulations
www.hc-sc.gc.ca/hpfb-dgpsa/onpp-bppn/labelling-etiquetage/regulations_e.html

National Academy of Sciences, Institute of Medicine: *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc*, National Academies Pr, 2000
www.nap.edu/catalog/10026.html

National Academy of Sciences, Institute of Medicine: *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium and Carotenoids*, National Academies Pr, 2000
www.nap.edu/catalog/9810.html

National Nutrient Databank Conference Steering Committee: *International Nutrient Databank Directory*. Produced for the 28th National Nutrient Databank Conference, University of Iowa, Iowa City, Iowa, USA, 2004
www.medicine.uiowa.edu/gcrc/nndc/NDB%20survey%20final%20version%2011-04.pdf

Standards Council of Canada: *Guidelines for the Accreditation of Agricultural and Food Products Testing Laboratories*. CAN-P-1587, 2003
www.scc.ca/en/publications/criteria/labs/agriculture.shtml

US Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory: *USDA National Nutrient Database for Standard Reference*, Release 17, 2004
www.nal.usda.gov/fnic/foodcomp/Data/SR17/sr17.html

Ibid: *USDA Table of Nutrient Retention Factors,* Release 5, 2003
www.nal.usda.gov/fnic/foodcomp/Data/index.html#retention

US Food and Drug Administration, Center for Food Safety and Applied Nutrition: *FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases*, 1998
http://vm.cfsan.fda.gov/~dms/nutrguid.html

US Food and Drug Administration, Department of Health and Human Services: Code of Federal Regulations Title 21, Part 101.108, Appendices C and D
www.access.gpo.gov/nara/cfr/waisidx_04/21cfr101_04.html