Section J-1
Part 1 – Evaluation Standard for the Manufacturing Process

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1 Control of Operation

1.1 Product Formulation

1.1.1 Product formulae

Current written formulae are available for each product produced and any factors in the product formulation that are critical to the delivery of a product of uniform nutrient composition are identified.

Rationale

Formulae provide a basis for control of both a product's processing mechanisms and its composition, including nutrient content, nutrition labelling and claims.

Inadequate identification of critical procedures and protocols or of critical ingredients and their specifications may indicate lack of awareness or control of critical factors. These inadequacies could result in inaccurate nutrient composition.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Written formulae are current and available for each product.
- ❑ The formulae contain ingredient information.
  - All ingredients are identified, including additives, added vitamins, minerals, amino acids (e.g., brand/supplier, concentration, type, etc.), and components of each.
  - Amounts of all ingredients are identified.

- ❑ Products are formulated to ensure accurate nutrition declarations.
  - If ingredient substitution ("and/or" ingredients) is permitted, the choice of the ingredients (i.e., the alternating use of substitutable ingredients) does not affect the nutrient content of the final product.
  - When the formula allows for the use of rework, maximum levels and acceptable sources of the rework are specified. The effects of rework on the nutrient content and consequently, the Nutrition Facts table, are taken into consideration in the development of the formulation.

- ❑ Factors critical to product composition:
  - Ingredients critical to product composition are identified with complete specifications and limits. (For example, common sources of errors include incorrectly identified edible oil ingredients, sweeteners, fibre ingredients and protein sources.)
  - Procedures and protocols for functions that are implicated in the production of products of uniform nutrient composition are documented. (For example, common

sources of error include failure to take into account moisture and/or nutrient losses/changes during baking, heating, drying, evaporation, and storage.)
- Ingredients and nutrients particularly susceptible to change/loss are identified. (For example, common problems include oxidation of highly polyunsaturated fatty acids, oxidation of vitamin C, and protein-sugar reactions (Maillard) in meat products.)

1.1.2 Nutritional requirements

The addition of vitamins, mineral nutrients and amino acids to food products is controlled to meet the requirements of the *Food and Drugs Act and Regulations*.

Foods for which nutrient content claims and health claims are made meet the compositional requirements of the *Food and Drug Regulations* [Sections B.01.503, B.01.600].

Rationale

The manufacturer has control over the formulation to ensure that all nutritional requirements and claims are met. Formulation controls are necessary to prevent hazards which could result from excesses, inadequacies and omissions of nutrients e.g., fortified foods and foods for which there are nutrition and/or health claims (e.g., Calorie-reduced, low sodium).

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Vitamins, mineral nutrients and amino acids are added to foods in accordance with the *Food and Drug Regulations* [D.03.002 and specific regulations].
- ❑ Added nutrients are food grade and from permitted sources.
- ❑ The manufacturer has specifications for nutrients.
- ❑ The manufacturer receives the following documentation:
  - nutrition information for each shipment of nutrient premix [B.01.404]; and
  - a certificate of analysis for each lot of nutrient.
- ❑ The manufacturer has verified and can demonstrate through calculations that added nutrients are used within the limits specified in the *Food and Drug Regulations*.
- ❑ Final products meet the compositional requirements for any nutrient content claim or health claim made on the label or in any advertisements.

1.1.3 Nutrient value declaration

All prepackaged products carry a Nutrition Facts table, other than permitted exemptions.

The declared nutrient values in the Nutrition Facts table are accurate throughout the period the label is in use, taking into consideration the required rounding and all sources of variation, including the natural variation of nutrients in food, variation in nutrient content due to processing and variations due to laboratory methods.

Declared nutrient values of individual lots of product have a high probability of meeting the Nutrition Labelling Compliance Test.
http://www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

The nutrient composition requirements for nutrient content claims and health claims are met throughout the shelf life of the product when held at recommended or usual storage conditions.

Rationale

Nutrient declarations and nutrient content claims are expected to be accurate for each specific product labelled. Many consumers and health professionals use nutrition information on food labels as part of the dietary management of chronic disease or conditions in which nutrition plays a role.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Prepackaged products declare a Nutrition Facts table in compliance with the *Food and Drug Regulations*.
- ❑ Label values have a high probability of being accurate and are rounded in compliance with the *Food and Drug Regulations* [column 4 of the tables to Sections B.01.401, B.01.402].
- ❑ Individual lots have a high probability of meeting the CFIA Nutrition Labelling Compliance Test throughout the period the label is in use. (See the *2003 Guide to Food Labelling and Advertising,* Section 6.11.)

The legal agent determines the nutrient value of products through one or more of the following methods or equivalent.

Method 1: Nutrient Analysis of "Finished Food"

Suitable for all foods
e.g., vegetable oils, protein in meat

Suitable for foods with nutrition and health claims
e.g., ensure nutrient is present at acceptable levels, "X% less" claims

When the legal agent relies on end product analysis, the following minimum specifications are met:

- ❑ The legal agent has a representative sampling plan that takes into account known sources of variation.
- ❑ The frequency of sampling is suitable for the product being analysed.
- ❑ The foods are analysed by qualified technicians using collaboratively tested AOAC methods of analysis or equivalent. (See *Validation of all options* below.)

Method 2: Use of a Representative Data Base* for "Finished Food"

Most suitable for single ingredient foods and less complex foods
e.g., eggs, honey, maple syrup, fruit, vegetables, meat, poultry, fish, seafood, canned vegetables, butter, and sugar

When the legal agent relies on finished food data bases, the following minimum specifications are met:

- ❑ The food accurately fits the description of the specific food in the data base.
- ❑ The data base was developed for labelling purposes and is consistent with Health Canada's *Guide for Developing Nutrition Labelling Values* or the FDA *Nutrition Labelling Manual – A Guide for Developing and Using Data Bases, 1998 edition:* http://vm.cfsan.fda.gov:80/~dms/industry.html#lab
- ❑ The sampling plan was carefully designed to get a representative sampling of the food available in the Canadian market place. For example, if the data base is national in scope, then samples should be taken from across the country.
- ❑ The data base is maintained and updated on a regular basis.

**Nutrition labelling data bases for finished food are defined as collections of nutrient data for specific products or commodities. The data bases may be compiled by a legal agent, an organization or a trade association of legal agents.*

Method 3: Use of an Ingredient/Recipe Data Base*

Suitable for multi-ingredient foods
e.g., bakery products

When the legal agent relies on ingredient data bases, the following minimum specifications are met:

- ❑ The legal agent can document the data source, (e.g., supplier's data used for each ingredient) and demonstrate that the data for each nutrient in the final product is accurate.
- ❑ The legal agent has procedures in place to ensure that the influence of processing factors, such as heating, drying, effects of pH, etc., are taken into account.
- ❑ The data base is maintained. The legal agent has procedures in place to ensure that the values in the ingredient composition data bases are reviewed and updated as needed. (For example, the data base is updated to reflect changes in ingredients or suppliers of ingredients.)
- ❑ The legal agent has procedures in place to ensure that nutrient values are product specific. (Nutrient data specific to one product formulation and process are not used for a similar formulation and process. For example, each of 18 macaroni and cheese dinners has its own nutrient data calculations.)
- ❑ The legal agent ensures that the nutrient values used for ingredients are not pre-rounded (i.e., the raw data from database is being used). When added together, multiple ingredients with nutrient values rounded down (e.g., 0.4 rounds to 0.0) will give lower values than is actually present.

**An "ingredient" or "recipe" data base is defined as a data base that is comprised of nutrient data from several sources. In these data bases, software is used to calculate label values for the final product from the combined nutrient content of ingredients that comprise a product's recipe, while taking into account nutrient and moisture losses during processing.*

Method 4: Use of Published Data *

Suitable for foods such as flour and rice

When the legal agent relies on published data bases, the following minimum specifications are met:

- ❑ The published data used is reliable.
- ❑ The published data is applicable to the product. (For example, nutrient data for pears packed in juice should only be used for that product and not for other similar products such as pears packed in light syrup.)
- ❑ Fortification levels meet Canadian requirements.

** Note: The legal agent may use published data as a basis for establishing nutritional values. However, most published data are not designed for nutrition labelling and it is the legal agent's responsibility to ensure that the values are accurate for the product.*

Method 5: Technical Expertise — Use of a Food Scientist or Other Expert in Nutrient Data

When the legal agent relies on nutrition labelling consultants, the following minimum specifications are met:

- ❑ The legal agent can supply the name and address of the consultant.
- ❑ The legal agent can supply an overview of what methods were used to determine nutrient values.
- ❑ The consultant should be able to show appropriate data sources and account for variance, statistics, and potential nutrient loss.

Other Options

The legal agent may use methods other than the above to develop nutrient values. In all cases, the legal agent should be able to demonstrate that the nutrient values are accurate.

Validation for all options:

- ❑ The legal agent has a validation system in place to affirm that the method or methods used to determine the nutrient content of their products will result in labels with accurate Nutrition Facts tables.

  The validation system should be overseen by qualified personnel, should include end product testing, and when applicable, validation of the data. The validation plan should also include shelf life stability validation.

Qualified Personnel

- ❑ Individuals or organizations responsible for verification are identified and are qualified.

Validation of Data

- ❑ Procedures are in place to validate (audit/ review) data such that final values have a high probability that all declared values will meet compliance criteria.

  The validation system reviews the appropriateness of the method(s) used, controls in place to ensure the specificity of the data, i.e., does the data accurately represent the ingredients/foods in use, and that data bases are updated as required, etc.

End Product Testing

- ❑ A system of end product testing is in place to verify that the values in the Nutrition Facts table are accurate and that the product is in within tolerance. The following factors should be taken into consideration in the design of the validation system.

  - Frequency: Frequency of testing is sufficient to substantiate nutrient values used in the Nutrition Facts table. Foods with variable nutrients would require increased frequency of testing compared to foods with a stable nutrient content.

- Choice of laboratory: The choices below are listed in order of desirability.
  - Canadian laboratory accredited by the Standards Council of Canada (SCC) that lists the testing of nutrients in foods in their scope (www.scc.ca),
  - Canadian laboratory knowledgeable in food testing,
  - In-house laboratory with qualified analysts or an outside lab that can demonstrate proficiency in producing quality data, or
  - Laboratory located at the American parent company or American laboratories.
- Laboratory methods:
  - The method is specific for the food. In some cases, methods are designated for specific foods *and* specific nutrients (e.g., protein in flour).
  - The method is an AOAC official method.
  - Where no AOAC method is available, other reliable validated methods may be used.
- Sampling:
  - Techniques used ensure that samples are representative of the product.
- Results:
  - The results are within tolerance of the declared values and if not, appropriate action is taken (i.e., reformulation, modification of Nutrition Facts table, tightening of processing controls, etc.)
  - Actual results correspond with the theoretical calculations and if not, the variation is justified.
  - When end product testing indicates non-compliance, corrective action should be taken in line with Section 1.7, "Deviation Control and Corrective Action".

Shelf life stability testing:

The legal agent has conducted stability analysis for selected nutrients in the final food with sufficient frequency to substantiate the maintenance of the nutrient content up to the best before date, expiration date or shelf life of the product. (The analysis should take into consideration packaging when subjected to normal conditions of storage and distribution.)

1.1.4 Composition/label accuracy

> The manufacturer has procedures to ensure that nutrition information on labels is accurate and meets the applicable requirements of the *Food and Drugs Act and Regulations.*

Rationale

Inaccurate Nutrition Facts tables, nutrition claims and health claims may pose a health risk to those under dietary management for chronic diseases such as diabetes, heart disease, high blood pressure, cancer or osteoporosis who are making food choices based on nutrient content. Inaccurate labels may also be considered false and misleading and in violation of Section 5.1 of the *Food and Drugs Act.* Inaccurate labels run counter to the objective of enabling consumers to make informed food choices to achieve healthy eating goals.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Procedures are in place to ensure that label information accurately represents product formulation and composition. The following are examples of such procedures:
  - Labels are reviewed by trained personnel for compliance with all pertinent Canadian legislation, including requirements for nutrition labelling, nutrient content claims and health claims.
  - Nutrition Facts table is verified for accuracy.
  - All new labels or modifications to labels are reviewed and verified for accuracy.
  - There is a system of communication between departments that ensures that any changes in formulation, suppliers or brands of ingredients result in an assessment review for any impact on labelling, composition or claims (for all formats of the specific product). If there is impact (specifically, on information in the Nutrition Facts table, nutrient content claims and health claims), consequent modifications are made as required.
  - All incoming labels are verified for accuracy/correctness.

1.2 Process Design

1.2.1 Process design

The manufacturer demonstrates the process is designed in a manner to ensure the composition of the product is constant and reflects the nutrient declarations.

Rationale

Written verification is necessary to demonstrate that each process used is adequate to ensure the composition of the product reflects the values declared on the label.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ For every product a written description of the process, including procedures, is available upon request.
- ❑ The process is established using accepted scientific methods. Details of actual experimental methods are available.
- ❑ All critical factors for each product, including the critical limits for each factor, are identified, tested and evaluated in the development of the process (e.g., heating, drying, freezing, cooling, etc.)

NOTE: The degree of testing and evaluation required is relative to the risk of the operation.

- ❑ Any changes to the process are assessed to evaluate if there has been an effect on the nutritional content of the food and appropriate action is taken to ensure that the Nutrition Facts table, nutrition and health claims are accurate.

1.3 Incoming Material Control

1.3.1 Ingredients

The manufacturer controls incoming ingredients to ensure that the quality and nutritional content of ingredients meets specifications at point of receiving.

Rationale

Control of incoming ingredients contributes to the production of a product with a consistent nutrient content.

Note: Specifications for nutrients are assessed in subsection 1.1.2, "Nutritional requirements".

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The manufacturer has written specifications and ensures that all components of the ingredients are declared.
- ❑ Purchasing specifications include a provision for compliance with the *Food and Drugs Act and Regulations.*
- ❑ Nutrition information accompanies each shipment of incoming ingredients [B.01.404].

Note 1: The nutrition information may be conveyed on an accompanying hard copy document with the delivery of the food.

Note 2: In the case of foods that are shipped to a purchaser on a continual basis, with no change to the formulation, documentation may be provided to the purchaser on the basis of the first shipment, without having to provide the information on an ongoing basis provided the purchaser agrees in writing to this arrangement. Any change to the nutrition information as a result of formulation changes or other influences would have to accompany the modified product with its first delivery after the change has occurred.

The manufacturer controls incoming ingredients through one of the following programs or equivalent.

Option 1 Periodic Evaluation of Incoming Ingredients

- ❑ A representative sample is taken to verify the accuracy of nutrition information or certificates of analysis at a scheduled frequency.

- ❑ The manufacturer maintains a documented history of adherence to specifications for each supplier, e.g., analytical results.
- ❑ A new history of adherence to specifications is established when a firm changes suppliers, purchases ingredients from a new supplier, purchases a new ingredient from an existing supplier or when spot checks do not agree with the certificate of analysis.

Option 2 100% Lots Inspected

- ❑ Each incoming lot is sampled according to a pre-determined sampling plan and analysed for adherence to specifications.

Option 3 Vendor Certification

When the manufacturer relies on vendor certification the following minimum requirements are in place:

- ❑ The manufacturer has documentation to demonstrate adequate knowledge of the supplier's process. This may include, for example: process flow charts, on-site evaluations, identification of critical control points, specifications, control limits, monitoring programs and frequencies, corrective action and verification procedures.
- ❑ The manufacturer has data to demonstrate the capability of the supplier's process to consistently manufacture within specifications. This may include process capability studies. Statistical process control charts for each critical control point must be available upon request from each supplier.
- ❑ Prior to implementation of a periodic monitoring program, the firm analyses an appropriate number of consecutive lots to establish an historical data base and confirm adherence to specifications.
- ❑ The manufacturer conducts periodic monitoring to verify adherence to specifications, e.g., annually.
- ❑ The manufacturer conducts vendor audits to validate the status of the vendor certification program.

Non-Conforming Ingredients:

- ❑ When ingredients do not meet specifications, the manufacturer investigates and identifies the root cause. If the ingredients do not meet specifications but have not been used, it is not considered a deviation. However, if it is possible that ingredients not meeting specifications have been used, the manufacturer should initiate deviation/corrective action as per subsection 1.7, “Deviations and Corrective Action.”

1.4 Product Preparation/Blending

1.4.1 Critical factor control

Critical factors in the product preparation/blending operation that could affect product composition and nutrient content are controlled.

Rationale

Inadequate control of critical factors could result in the production of a variable product that may not conform to product specifications. Consequently, the list of ingredients, nutrition declaration and nutrient content claims may be incorrect.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The manufacturer has controls in place to ensure that product formulation and operating procedures are followed. Critical areas in the product preparation/blending operation include, but are not limited to the following:

  Product preparation/blending
  - measuring, e.g., weighing, volumetric control (metering);
  - blending – adequate blending to ensure consistent distribution of ingredients;
  - temperature treatment control (e.g., heating, blanching, defrosting, cooling) since temperature treatment may result in nutrient loss, and
  - pH/acidity control (e.g., pH measurements, titratable acidity) since certain nutrients are affected by the pH of the substrate.

  Composition
  - controls to ensure that the product formulation is followed and that only product substitution sanctioned by the formulation occurs; and
  - if "rework" product is used, there is provision for its use in the formulation and its use does not render the list of ingredients nor the nutrition label inaccurate.

  Nutrient addition
  - controls to ensure nutrient levels comply with regulatory and label requirements including:
    - clear identification of each nutrient,
    - proper storage and handling to maintain nutrient potency,
    - accurate measurement, and
    - adequate blending for homogeneity.

1.5 Process Control

1.5.1 Control of critical factors

All critical processing factors are controlled to ensure the compositional integrity of the product.

Rationale

To produce foods that consistently meet specifications, manufacturers need to identify and control processes and procedures that are critical to production

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The manufacturer ensures all critical processing factors that may affect nutrient content or the ingredient list (identified in subsection 1.1.1) are controlled within defined limits to maintain label accuracy (e.g., heat treatment, time/temperature variables – pasteurizing, retorting, curing.)
- ❑ The manufacturer monitors the critical factors at a scheduled frequency. The frequency of monitoring will depend on the type of process and associated risk.

1.6 Labelling Control

1.6.1 Control factors

The manufacturer has controls in place to prevent mislabelling.

Rationale

Control of labelling is important to ensure that the correct label is applied to each product. Use of incorrect labels may result in inaccurate information being provided to consumers, and may also result in potential health hazards.

Assessment Criteria:
Verify that the following requirements have been met.

The manufacturer has controls in place to prevent the mislabelling of products. Typical controls may include the following:

- ❑ During changeovers, product types are effectively separated (e.g., appropriate breaks between products, use of marked containers or visual inspection to ensure products are not mixed prior to labelling.)
  - Different product labels and/or prelabelled packaging are effectively separated.

- Identifying marks and/or colours are used on labels to ensure correct labels are being loaded into the labeller.
- Tops and bottoms of label bundles are visually checked for mixed labels prior to use.
- Controls are in place to ensure the product being supplied or added to the labelling operation corresponds to the labels in use.

1.7 Deviation Control and Corrective Action

1.7.1 Deviation control

> Where critical limits are exceeded or defects occur which could affect composition or nutrition declarations, procedures are in place to identify, isolate and evaluate products.

Rationale

Product composition may be affected when processes deviate from critical limits and procedures, or when defects occur. A failure to adhere to procedures, or inadequate deviation procedures, could result in the sale of non-compliant products.

Assessment Criteria:
Verify that the following requirements have been met.

❑ The manufacturer controls deviations by identifying the deviation, isolating affected products and evaluating affected products. Verify the following:

Identification of deviation

❑ The manufacturer has a system in place to identify deviations when they occur.

Isolation of affected product

❑ The manufacturer has effective procedures in place to isolate, clearly mark and control all product manufactured during the deviation period.
- All unsatisfactory product is isolated back to the point where the process was last in control. This could be beyond the last satisfactory record.
- Isolated product is clearly marked, e.g., tags are firmly attached with the following information: hold number, product identity, quantity, date held, the reason for the hold, and the name of the person holding the product.
- The manufacturer maintains control of the product from the hold date to the date of final disposition.

Evaluation of affected product

- ❑ Product evaluation is conducted by a qualified person, e.g., process deviations are evaluated by qualified personnel.
- ❑ Disposition of affected product, (e.g., sorting of suspect lots, disposal, etc.) is conducted in an appropriate manner by adequately trained personnel.
- ❑ Evaluation is adequate to detect potential health hazards related to inaccurate nutrient declarations and nutrient claims. For example, sampling is adequate to identify the extent of the problem, the tests are appropriate, the judgement is based on sound science and the product is not released until the evaluation has determined that no potential health hazard exists.

1.7.2 Corrective action

Corrective action taken following any deviation is effective to ensure the safety of the product and to prevent recurrence of the deviation.

Rationale

Appropriate corrective action will address the root cause of deviations. To prevent recurrence, the action must be followed-up: monitored and reassessed to ensure that the corrective action taken is effective.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The manufacturer's corrective action program includes the following:
  - Investigation is completed to determine the cause of the deviation.
  - Effective measures are taken to prevent recurrence of the deviation.
  - The manufacturer verifies the effectiveness of the corrective action taken.

2. Equipment

2.1 General Equipment

2.1.1 Design and installation

All equipment and utensils are designed, constructed and installed to function as intended and to achieve product specification.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Equipment is designed, constructed and installed to ensure that it is capable of delivering the requirements of the process.

- ❑ Equipment is designed, constructed and installed to ensure that it is capable of producing a product that meets specifications. e.g., composition, labelling, etc.

2.1.2 Equipment maintenance and calibration program

An effective maintenance and calibration program is in place to ensure that equipment performs consistently as intended.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The manufacturer has an effective written preventative maintenance program to ensure that equipment that may have an impact on product composition functions as intended. This includes:
  - a list of equipment requiring regular maintenance, and
  - defined maintenance procedures and frequencies. For example, equipment inspections, adjustments and part replacements are based on the equipment manufacturer's manual or equivalent, or are based on operating conditions that could affect the condition of the equipment.
- ❑ The preventative maintenance program is adhered to.
- ❑ Written protocols, including calibration methods and frequencies, are established by the manufacturer for equipment monitoring and/or controlling devices that may impact on product composition.
- ❑ Maintenance and calibration of equipment is performed by appropriately trained personnel.

2.1.3 Instrumentation (e.g., scales, metering devices)

Instrumentation is designed, constructed, installed and maintained such that the equipment is capable of delivering the required process to ensure product composition.

Rationale

Inadequate processing, food additive addition, nutrient addition or composition may result from improper design, installation, calibration or maintenance of instruments. These inconsistencies and/or errors may affect the final nutrient content of the product.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Instruments which control factors critical to product composition are designed, installed, constructed and calibrated as necessary to ensure that they function as intended.

- ❑ The following are some examples of instrumentation that may be required to control factors critical to the composition:

  Scales and metering devices
  - The sensitivity is appropriate to the use.
  - Scales and metres are calibrated as necessary to ensure accuracy at all times.

  Other instrumentation
  - Other specialized instrumentation necessary for the control of critical factors are in place and calibrated as necessary, e.g., pH metres, temperature measuring devices.

3. Personnel

3.1 Training

3.1.1 Technical training

To ensure the accuracy of nutrition declarations on the label, personnel are trained such that they have adequate technical knowledge and understanding of the operations or processes for which they are responsible.

Rationale

Accurate nutrition labelling is highly dependant on the ability of personnel to perform their tasks.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Training is appropriate to the complexity of the manufacturing process and the tasks assigned. For example:
  - Personnel are trained to understand the importance of the critical factors for which they are responsible, e.g., the critical limits, the procedures for monitoring, the action to be taken if the limits are not met, nutrition labelling requirements and the records to be kept.
  - Personnel responsible for the maintenance of scales and metering devices are trained to identify deficiencies and to take the appropriate corrective action.
  - Operators are trained to have current knowledge of equipment and process technology, e.g., apprenticeship training, pasteurization operation training, feed pump calibration training.
  - Personnel responsible for maintenance of equipment impacting on nutrition content and declaration have been appropriately trained to identify deficiencies and to take the appropriate corrective action, e.g., in house repairs, contract

repairs. Individuals performing maintenance on specific equipment are appropriately trained.

4. Transportation and Storage

4.1 Handling, Storage and Transport

4.1.1 Control factors

Ingredients and finished products are handled, stored and transported in a manner that minimizes nutrient loss.

Rationale

Certain nutrients are very sensitive to environmental stresses, including heat and light. Abuse of ingredients and finished products may lead to nutrient loss and, thus, inaccurate nutrient labels.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Ingredients and finished products requiring refrigeration are stored and transported at 4^0 C (39^0 F) or less and are appropriately monitored. Frozen ingredients and finished products are stored and transported at temperatures that do not permit thawing and are appropriately monitored.
- ❑ Ingredient and finished products rotation is controlled to prevent deterioration and spoilage.
- ❑ Humidity sensitive ingredients and finished products are stored and transported under appropriate conditions to prevent deterioration.

5. Records

5.1 General Records

5.1.1 General record requirements

Information is recorded in a manner to represent an accurate history of the product or process. Records are retained for the required period of time.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Records are legible, permanent and accurately reflect the actual event, condition or activity.

- ❑ Errors or changes are identified in a manner such that the original record is clear, e.g., strike out with a single stroke and initial the correction/change.
- ❑ Each entry on a record is made by the responsible person at the time that the specific event occurred. The completed records are signed and dated by the responsible person.
- ❑ Critical records are signed by a qualified individual designated by management prior to distribution of the product. All other records are reviewed at an appropriate frequency to provide an early indication of potentially serious deficiencies.
- ❑ Records are retained for at least one year after the expiry date on the label or container or if there is no expiry date, for at least two years after the date of sale.
- ❑ Records are maintained and are available upon request.

Note: When records are kept electronically, an electronic signature is acceptable.

5.2 Product Formulation

5.2.1 Nutrient value declaration records

Records are available to demonstrate the validity of the declared nutrient values

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Records include nutrient calculations that meet the following criteria:

Laboratory analysis

- Records include laboratory tests that demonstrate the analyses were appropriate to the operation and food in question. Minimum declared nutrient values records include:
  - nutrients analysed;
  - frequency of testing;
  - sampling – records of when and where the samples were taken and what part of production the samples represent (e.g., lot number, best before or expiry date, production date, shift, line, time, etc.);
  - laboratory used and their qualifications for doing testing (e.g., accreditation by SCC for testing nutrients, etc. – see Section 1.1.3 , "Validation of all options");
  - laboratory methods used (see Section 1.1.3, "Validation of all options");
  - analytical results – when results are not within tolerance, records indicate: 1) specific lots involved, and 2) actions taken to correct the situation and prevent re-occurrence (e.g., reformulation, modification of Nutrition Facts table, tightening of processing controls, etc.);
  - comparison of actual results to theoretical calculations – when discrepancies in results occur, the variation is justified; and
  - results are within tolerance of the declared values and if not, appropriate action was taken (e.g., reformulation, modification of Nutrition Facts table,

tightening of processing controls, etc.)

Records of data base maintenance

- identification of the data base(s) and/or software(s) – including the specific version – in use;
- record of all changes that may affect the accuracy of the data base (e.g., changes in formulation/recipe, food yields and retention factors, etc.);
- records of updates to the data base values and software calculations; and
- records of quality control audits.

5.3 Control of Operation

5.3.1 Process design records

Records are available to demonstrate the adequacy of procedures and methods used in process development.

Rationale

If records are absent or inadequate, it is difficult or impossible to verify that critical factors and critical limits are adequate to produce a product with a consistent nutrient content.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Records are available to verify that reliable procedures have been followed in designing the process.

5.3.2 Incoming material control records: ingredients

The manufacturer has records available that demonstrate the adequacy of control over incoming ingredients.

Rationale

If records are absent or inadequate, it is difficult or impossible to verify the manufacturer's control over nutrient content of incoming ingredients.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The manufacturer meets the minimum record requirements for:
  - Monitoring all incoming ingredients,
  - Specific “option” or program in place used to control incoming ingredients, and

- Non-conforming incoming materials.

Note: See section 1.3.1 for program options available for controlling incoming ingredients.

Monitoring all incoming ingredients

- Nutrition information is available for each shipment of incoming food product [B.01.404]. The most current version of the nutrition information for each food is on file. The manufacturer is able to demonstrate that this information is being used to ensure that product formations and data bases are accurate and up to date.

Control of Incoming Ingredients

Option 1 Periodic evaluation of incoming ingredients

- History of adherence to specifications is kept for *each* supplier.
- Records of product testing, including analytical results are kept.

Option 2 100% lot inspection

- Analytical results are kept for each incoming lot.

Option 3 Vendor certification

- Records are kept to demonstrate knowledge of the supplier's process (e.g., process flow charts, critical control point identification, process specifications, critical limits, monitoring and verification reports, corrective action plans and reports, and on-site evaluation reports.)
- Records are kept to demonstrate the capability of supplier's process (e.g., capability studies.) Statistical process control charts are available upon request.
- A historical data base is kept (e.g. analytical results on consecutive lots.)
- Periodic monitoring is undertaken (e.g., analytical results.)
- Supplier audits are undertaken (e.g., audit reports.)

Non-conforming incoming materials

Records for non-conforming incoming ingredients include the following information:

- The non-conforming material is identified.
- The deficiency is identified.
- Record of preventative and corrective action taken.

5.3.3 Product preparation/blending records

Critical factor control records are maintained and are available on request.

Rationale
If records are absent or inadequate, it is difficult or impossible to verify the manufacturer's control of critical factors in preparation/blending.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Records are available to demonstrate control of product preparation/blending, including records to demonstrate adherence to critical limits specified in the formula (e.g., records for critical factors specified in the process, for the filling, and for nutrients in foods.)

5.3.4 Process control records

Written records that adequately reflect the control of critical processing factors are available upon request.

Rationale
If records are absent or inadequate, it is difficult or impossible to verify the safety of the process and product composition.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The manufacturer has records that demonstrate control of the critical processing factors and the composition of the product.
- ❑ Deviations are noted on the operator's records.
- ❑ If product formulation provides for "and/or" ingredients, records are kept to indicate which ingredient is used for each particular batch or lot.

Note: Minimum information required on records may vary depending on the type of process.

5.3.5 Deviations and corrective action records

Records are available to demonstrate the control of deviations and the effectiveness of corrective actions taken.

Rationale

If records are inadequate, it is difficult or impossible to verify the manufacturer has control of deviations and takes appropriate corrective action.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ The following minimum information is recorded in the deviation and corrective action records:

  Deviation/hold
  - product/code,
  - date produced/held/released,
  - reason for the hold,
  - amount of product held (e.g., back to the point where the process was last in control),
  - results of evaluation/sort (e.g., amount analyzed, analysis report of the number and nature of defects),
  - disposition of held product (e.g., amount sorted, destroyed, employee sales, distress or salvage, reconditioning and retail sales),
  - signature of personnel responsible for hold and evaluation, and
  - signed authorization for disposition

  Corrective action
  - cause of deviation identified,
  - corrective action taken to correct deficiency,
  - follow-up/assessment of effectiveness of corrective action,
  - date corrective action was taken and verified, and
  - signature of person responsible

5.4 Equipment

5.4.1 Maintenance and calibration records

Records are available to demonstrate adherence to the maintenance program for critical equipment.

Rationale

Records permit verification of the effectiveness of the equipment maintenance and calibration program.

Assessment Criteria:
Verify that the following requirements have been met.

- ❑ Typical information expected in maintenance records for critical equipment includes:
  - identification of equipment,
  - maintenance activity,
  - date,
  - person, and
  - reason for activity.

- ❑ Typical information expected for calibration records for critical equipment includes:
  - identification of equipment,
  - date,
  - person, and
  - calibration results.