International Standard for Certified C.L.E.A.N.™ Food Certification

Published by

a 501(c) 3 Not-For-Profit Organization

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Version
CLEAN-1.10-03.2024
C.L.E.A.N Food Certification

The International Center for Integrative Systems (ICIS) (See below and www.integrativesystems.org) has developed a standard that aims to verify the claims and support the growth of the community of raw and healthy food while enabling transparency for consumers, retailers, manufacturers and the regulatory community. The standard may be used for conformity assessment, purchaser specifications, and public education. ICIS offers certification of products, services, and companies in conformance with its standards.

International Center for Integrative Systems (ICIS)

The International Center for Integrative Systems aims to be the world's leading center pioneering scientific research for developing new methodologies for integrating, understanding, and visualizing large scale complex systems such as media & telecommunication infrastructure, healthcare, transportation systems and innovation & governance systems.

The Center's activities include:

- Scientific Research
- Lectures and Open Forums
- Education Initiatives with Universities
- Curriculum Development
- Systems Visualization
- Publishing

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Stakeholders including the following were involved in providing feedback, participating in public hearings creation of this standard:

- Food Processors and Manufacturers
- Food Industry Trade Associations
- Farmers/Food Producers and Growers
- Public Interest and Consumer Advocacy Groups
- Food Distributors and Retailers
- Restaurants
- Federal, State and Regional Government Agencies
- Standards Setting Organizations
- Certifying and Accrediting Organizations
- Academicians
- Nutritionists, Health Care Workers and Physicians
- Consumers

ABSTRACT

This is a standard for certification of packaged foods. While the number of food manufacturers claiming to offer wholesome, healthy packaged foods is growing, there is no clear understanding of what constitutes healthy, “raw” and ”clean” foods. Also, more and more people are incorporating what they believe to be raw foods into their diets principally for health and taste reasons. But there is debate and confusion over what actually constitutes “raw” and what the characteristics should be to maintain a food’s ”raw” quality at point of sale and also protect consumers from food borne diseases. This consensus-based standard’s criteria incorporate the inputs from the food stakeholder community of consumers, public interest groups, growers/farmers, food processors, trade associations, food retail stores, restaurants, regulatory agencies and academicians. The criteria focus on three categories - Safety, Minimal Processing and Bioavailability of nutrients. The Safety criteria are that the item is produced under the auspices of: (1) Hazard Analysis and Risk-Based Preventive Controls (HARPC) Plan compliant with FSMA Final Rule for Preventive Controls for Human Food, (2) The manufacturer uses Current Good Manufacturing Practices (GMP) of the FSMA Final Rule, (3) The manufacturer registers its food processing facility with the Food and Drug Administration (FDA), and, (4) No food items are packaged which are toxic when raw (uncooked). The Minimally Processed criteria are that the ingredients and completed food are: (1) Certified Organic under the USDA National Organic Program (NOP); (2) Non-Genetically Modified Organisms (non-GMO); and, (3) Not irradiated. The Bioavailability criteria are that the product’s key molecules collectively maintain their enzymatic activity as verified and scored through a range of 0 to 20, through CytoSolve® testing (CS® Tested™) for enzymatic activity. Based on these criteria, the Certified C.L.E.A.N. imprimatur is derived.

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1.0 INTRODUCTION

The food industry is undergoing explosive growth as well as a concomitant scrutiny by various stakeholders including consumers, regulatory agencies, retailers and manufacturers.

When industries emerge and grow, such fundamental questions and scrutiny are not uncommon. The best approach to address critical questions of stakeholder groups is to develop consensus-based industry standards and processes for certification. Moreover, history demonstrates that when such standards are developed *bottom up,* starting with and involving the entire stakeholder community, rather than initiated by government or regulatory agencies (*top down*), they have served to advance the industry and address stakeholder concerns.

To this end, *RawFoodCertified.org* and *CleanFoodCertified.Org* were formed, as 501(c) 3 projects of the International Center for Integrative Systems in early 2014. ICIS began developing a framework based on a systems approach that integrates quantitative and qualitative measures, in a *Multiple Criteria Decisions Analysis (MCDA)* model, to define "Raw" and "Clean". Starting in May of 2014, ICIS began consultations, interviewing and holding individual and group meetings with stakeholders from the raw foods community.

This standard captures the efforts of ICIS and key leaders and experts in the food community to develop food certification processes that define "Raw" and "Clean" foods.

2.0 SCOPE OF THIS STANDARD

The certification of foods in this document is limited to certain food groups and dietary supplements. These include vegetarian foods (plant matter), food of animal origin which can be sustainably and humanely harvested from animals such as meat from livestock, milk from mammals, eggs from birds and honey from bees, and minerals that have been minimally processed, are safe, shelf/refrigerator/freezer stable and have their nutrients in a bioavailable form. The standard includes packaged foods, juices, soups, soy and nut beverages, and prepared foods such as pickles, relishes, slaws, gazpachos, salsas and guacamoles. The standard, at this time, does not cover salads or sprouts (harvested vegetables with no further processing other than washing and packaging). The standard also does not cover raw meat, fish or shellfish.

The food processor seeking certification must be recertified under this standard annually in order to use the Certified C.L.E.A.N® imprimatur on their product package and in their advertising. Certification under this standard covers a specific packaged food product at one facility only. A product is the same list of ingredients (other than flavor variations) undergoing the same processing steps and temperatures regardless of ultimate package size. Other food products at the same facility must be certified separately. If the manufacturer makes the same food product in multiple locations, all locations must be certified for the product to bear the Certified C.L.E.A.N.® imprimatur.

3.0 KEY ELEMENTS OF THE STANDARD

The three unique core concepts defining this food certification are: (1) Safety, (2) Minimally Processed and (3) Bioavailable Nutrients as noted in Fig. 1, below.

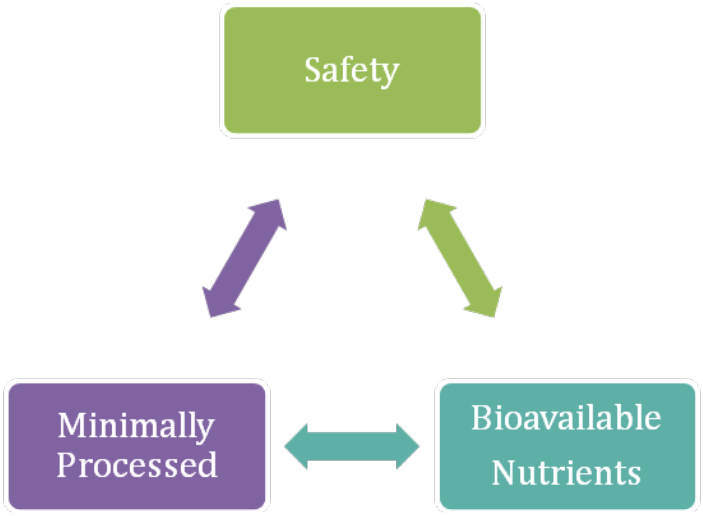

Fig. 1 – Three key elements of Raw Food Certification.

3.1 Safety

- HARPC – Hazard Analysis and Risk-Based Preventive Controls[i]
- GMP – Good Manufacturing Practices[ii]
- COA - Certificate of Analysis
- Registered with the US Food and Drug Administration (FDA)[iiiiv]
- Post Packaging Product Shelf-Life Testing

3.2 Minimally Processed

- Organic Certified[v]
- Non-GMO[vi]Below 212º Fahrenheit

3.3 Bioavailability

- Analyzed by CytoSolve (CS® Tested™) on a score ranging from 0 to 20 for enzymatic activity

4.0 SAFETY CRITERIA

Food borne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year[vii]. There are approximately 1,000 reported disease outbreaks (local, regional, and national) each year. Food pathogens are destroyed by, among other measures, elevated temperature. However, excessive heating also affects food, so to be both safe and raw a rigorous line of prophylaxis must be maintained by food producers. Foods can still be considered 'raw' as long as the temperature does not destroy the available nutrients in the food. Therefore there must be a careful balance between heating to the point of killing pathogens or heating to dehydrate to make the food shelf stable, while still maintaining the qualities of raw foods.

A large part of the safety issues are addressed with a HARPC Plan. HARPC plans provide a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can otherwise cause the finished product to be unsafe. The HARPC plan includes measures to reduce these risks to a safe level.

4.1 Hazard Analysis and Risk-Based Preventive Controls (HARPC) Plan

Final Rule of Food Safety Modernization Act describes HARPC as: "The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice."

The HARPC system clearly identifies food safety problems and also where and how they can be controlled or prevented. To assure that these actions are executed regularly and consistently, they have to be described and people who are responsible for their execution have to be trained. A record-keeping system has to be developed to provide documentation for all actions and measurements.[viii]

Under these directives:

4.1.1 The food processor must develop a HARPC Plan for each food product prepared**.**

4.1.2 The HARPC Plan must require that the food processor:

4.1.2a Conduct a hazard analysis.

4.1.2b Identify critical control points (CCPs) and develop and implement risk-based preventive controls at the critical points of the manufacturing process.

4.1.2c Establish monitoring procedures.

4.1.2d Establish corrective actions.

4.1.2e Establish verification procedures.

4.1.2f Establish record-keeping and documentation procedures.

4.1.2g Reanalyze the HARPC system: every three years; when there is a

significant change in the facility; and when threats are identified by the Department of Homeland Security.

4.1.3 The HARPC plan must be audited by a third party which is an accredited certifier under ISO 22000 or a member of the Global Food Safety Initiative. The HARPC audit must include the measurement of temperature and time for processing each ingredient and/or the produced food product. This becomes an important component in providing the input data for Minimally Processed and Bioavailability criteria of the standard.

To be eligible for C.L.E.A.N. certification, a food manufacturer must have a HARPC plan or an equivalent that satisfies the above directives.

4.2 Registration of the food processing facility with the Food and Drug Administration (FDA)

4.2.1 If not already registered and the food production facility is within the United States, register at the FDA website http://www.registrarcorp.com/fda-food/usregistration/domestic-food-facility.jsp?lang=en .
4.2.2 If not already registered and the food production facility is outside of the United States, register at the FDA website http://www.registrarcorp.com/fda-food/registration/food-facility.jsp?lang=en .

4.3 Good Manufacturing Practices (GMP)

4.3.1 GMP is a requirement of the FDA and a GMP inspection or audit is administered by a regulatory agency. The food processor must demonstrate that they have passed a Good Manufacturing Practices inspection either through documentation provided by the FDA or through the World Health Organization COPP or TRS 823, 863.

4.3.2 The GMP audit must include the measurement of temperature and time for processing each ingredient and/or the produced food product. This becomes an important component in providing the input data for Minimally Processed and Bioavailability criteria of the standard.

4.3.3. If the HARPC plan (or equivalent) addresses the GMP aspects, that will be considered satisfactory towards meeting the GMP criterion for certification.

4.4 Certificate of Analysis (COA)

4.4.1 The food processor must provide a certificate of analysis (COA) for each ingredient it receives which it uses to make raw packaged foods.
4.4.2 The COA must come from a lab that is accredited through ISO 17025, the National Voluntary Laboratory Accreditation Program (NVLAP) or some other voluntary or mandatory (varies by state) accreditation program.
4.4.3 The COA needs to define frequency of tests per ingredient lot, include pathogens, mold, bacteria etc. to be tested for.
4.4.4 The COA also becomes an important component in providing the input data

for Minimally Processed and Bioavailability criteria of the standard.

4.4.5 The COA must not include any of the items in Appendix A in raw (uncooked) form as they are toxic or poisonous in their raw form.

4.4.6 The COA may include any of the natural or synthetic compounds on the USDA NOP National List which is reprinted in Appendix B.

4.5 Post-Packaging Product Shelf-Life Testing

4.5.1 To the extent that post packaging shelf life testing is not done as part of the HARPC, GMP audits or FDA inspections, finished product safety and shelf life testing and analysis will be employed to determine Expiration Date, Best by Date, and Sell by Date for a food product.

4.5.2 The laboratory performing this testing will be accredited through ISO 17025, the National Voluntary Laboratory Accreditation Program (NVLAP) or some other voluntary or mandatory (varies by state) accreditation program.

4.5.3 The parameters tested for may include:

4.5.3a Food-borne micro-organisms such as Listeria, Salmonella, Campylobacter, E.Coli, Yeasts and Molds, Staphylococcus Aureus, Bacillus Cereus, Lactic Acid Bacteria.

4.5.3b Total viable count

4.5.3c Enterobacteriaceae

4.5.3d Moisture content

4.5.3e Acidity levels - pH

4.5.3f Water activity

4.5.3g Fat rancidity

4.5.4. To be eligible for C.L.E.A.N. certification, the manufacturer must at minimum, have established any one of a) Best By Date, b) Sell By Date, or c) Expiration Date.

5.0 MINIMALLY PROCESSED CRITERIA

The multiple processes conventional foods undergo from farm to table are so extensive and debilitating that many argue that foods, thus produced, are nutrient barren and flavorless or dull. In many ways, ‘raw’ is the opposite of cooked and processed foods and so a standard for raw seeks foods that are minimally processed. Some foods must be processed to provide for consumer safety. The criteria that evidence minimally processed for this standard are **Organic** and **Non-GMO.**

5.1 Organic

All prepared packaged foods seeking certification under this standard and ingredients must be certified organic under the USDA National Organic Program (NOP) (or an equivalent program that requires at least 70% of the ingredients to be organic), and have the following attributes:

5.1.1 have not been grown with artificial fertilizers

5.1.2 have not been treated with pesticides, herbicides or fungicides

5.1.3 use natural inputs and/or approved synthetic substances on the National

List (Appendix B)

5.1.4 have not been grown in chemical sludges

5.1.5 have not been irradiated

5.1.6 are grown and managed under an Organic System Plan

Natural aquatic ingredients, like seaweed, or those developed using aquaculture, are exempt from being certified as Organic. In dietary supplements, minerals are exempt from being required to be certified as Organic.

For products such as honey, maple syrup, etc. that cannot be certified under USDA NOP, if the levels of pesticide/herbicide/fungicide in a product are below EPA and/or USDA NOP guidelines, then such product should satisfy the Organic criteria.

5.2 Non-GMO

A genetically modified organism (GMO) is any organism whose genetic material has been altered using genetic engineering techniques beyond ordinary breeding and cross breeding techniques. This standard does not allow GMO food products to be certified since they have been manipulated beyond regular natural selection. All prepared packaged foods seeking certification under this standard and the ingredients in same should not contain foods that are derived from genetically modified organisms (i.e. they must be non-GMO) as evidenced by certification under the USDA NOP.

5.2.1 In case you are using any ingredient in this list of crops that currently include genetically modified varieties: http://www.nongmoproject.org/learn-more/what-is-gmo/, you must verify by providing documentation that you are not using genetically modified versions of those ingredients.

5.2.2 In the case where the USDA Organic Certification does not certify that all the top 10 ingredients are non-GMO (for examples for USDA "Made With Organic Ingredients" certification wherein only 70% of the foods need to be organic) and the COAs do not certify that the top 10 ingredients are non-GMO then the manufacturer will have the top 10 ingredients tested for GMOs using a laboratory that complies with the requirements set forth in the Non-GMO Project Standard and/or a laboratory that is accredited through ISO 17025, the National Voluntary Laboratory Accreditation Program (NVLAP) or some other voluntary or mandatory (varies by state) accreditation program.

Note: All agricultural ingredients in the product must be either raw or not commercially available in raw form. All non-organic agricultural ingredients must not be genetically engineered; irradiated; produced from sewage sludge; or be produced with a volatile synthetic substance. All non-agricultural ingredients and processing aids used must be approved on the National List (see Appendix B).

6.0 BIOAVAILABILITY OF NUTRIENTS CRITERIA

Broadly defined, Bioavailability refers to the proportion of a nutrient that is absorbed from the diet and used for normal body functions, participating in and supporting many

metabolic pathways. Bioavailability of a nutrient is governed by external and internal factors. External factors include the food matrix and the chemical form of the nutrient in question, whereas gender, age, nutrient status and life stage (e.g. pregnancy) are among the internal factors. Because aspects such as nutrient status also determine whether and how much of a nutrient is actually used, stored or excreted, some definitions of Bioavailability restrict themselves to the fraction of a nutrient that is absorbed.[ix]

The Bioavailability of macronutrients – carbohydrates, proteins, fats – is usually very high at more than 90% of the amount ingested. On the other hand, micronutrients, i.e. vitamins and minerals, and bioactive phytochemicals (e.g. flavonoids, carotenoids) can vary widely in the extent they are absorbed and utilised. If they are denatured and destroyed by food processing procedures, obviously they are not biologically available.

This standard deals with the bioavailability of micronutrient molecules in foods.

Besides the basic nutritional building blocks of proteins, amino acids, sugars, carbohydrates and fatty acids, there are specific health attributes to specific proteins, terpenoids and fatty acids. There is a myriad of beneficial proteins, enzymes, vitamins, cytochromes, phytochromes, antioxidants and terpenoids, which exists if food is grown organically and harvested and processed at ambient temperatures. These compounds may not be present in GMO plants nor in plants grown in nutrient depleted soils, which are chemically fertilized. Many of these same compounds denature (permanently lose effectiveness) and disappear at the elevated temperatures required of cooking.

6.1 How Bioavailability is Determined

For a product, using the ingredient data from the certificate of analysis of both type and weight, and the processing temperature from the HARPC or GMP audit, the top 10 ingredients, which are non-water and non-National List (USDA NOP) ingredients, are itemized. For each ingredient in this list of up to 10 ingredients, that will include proteins, enzymes, and essential fatty acids, the top three molecules by weight per ingredient are then itemized to create a list, for a total of up to 30 molecules per food product (3 molecules times 10 ingredients).

This listing of up to 30 molecules is submitted for CytoSolve® testing (CS® Tested) for an enzymatic activity analysis to receive an enzymatic activity score. The score is a number ranging from 0 to 20. The CytoSolve® testing (CS® Tested) process is executed per the CS 1.0-4.2015 Draft Standard.[x]

While heating an ingredient or food product is permitted at high temperatures, if you do so for longer than a very brief instant of time, the probability is high that the enzymes will have been denatured and will not meet the requirements of 6.1 for enzymes to remain active and viable. Section 6.2 provides guidelines for increasing the probability for enzymatic activity in the finished product.

6.2 Suggestions for Heat Treatment to Retain Bioavailability

The following guidelines are offered for maximum heating temperatures and times to help ensure that the majority of enzymes do not become denatured and remain viable.

6.2.1 heated to no more than 118ºF for an extended period of time
6.2.2 heated for more than 5 minutes to no more than 161ºF
6.2.3 heated to 165ºF for no more than 15 seconds
6.2.4 heated to 175ºF for no more than 10 seconds
6.2.5 heated to 180ºF for no more than 5 seconds
6.2.6 heated to 200ºF for no more than 2 seconds

Following the above guidelines is not a guaranty that the food item will receive a high score for Bioavailability. This will only be ascertained after the product data has been submitted for CS® Testing.

7.0 NAMING OF THE CERTIFICATION PROGRAM AND THE IMPRIMATURS

For products to be Certified C.L.E.A.N.:

- They must be Conscious, which means they must be 100% safe.
- They must be Live, which means a significant amount of the ingredients (at least 70%), must be organic.
- They must be Ethical, which means the ingredients must be 100% non-GMO.
- They must be Active, which means the ingredients must have a high amount of bio-available enzymes based on testing using the CS® Tested process.
- They must be Nourishing, as determined by ANDI Score.

8.0 CALCULATION OF C.L.E.A.N.

This section describes the calculation of the scores to determine whether a product will be Certified C.L.E.A.N.

8.1 Certified C.L.E.A.N. Determination

The following mechanism is used to determine what score a product will receive to be Certified C.L.E.A.N.. The score can range from 0 to 100.

There are 5 aspects of this scoring. The sum of these 5 aspects must equal 80 or more for a product to be Certified C.L.E.A.N.

The first aspect is **Conscious**: The score for Conscious is either a 0 or 25. If the product is 100% safe (satisfies SAFETY CRITERIA explained in 4.0) then it will receive a score of 25; otherwise it will receive a 0.

The second aspect is **Live**: The score for Live may range between 0 and 20, and is determined by the percentage of ingredients by weight that are organic (as explained in 5.1) in the product.

The third aspect is **Ethical**: The score for Ethical is either a 0 or 25. If the product is 100% Non-GMO (satisfies NON-GMO requirement explained in 5.2) then it will receive a score of 25; otherwise it will receive a 0.

The fourth aspect is **Active:** Based on CS® Testing, this score can range from 0 to 20.

The fifth aspect is **Nourishing**: The score for Nourishing ranges between 0 and 10 based on the ANDI score, determined by the percentage of ingredients, by weight, in the product. For dietary supplement, ANDI Score requirement is not applicable as it is only suitable for fruit and vegetables. Instead, alternate criteria such as Oxygen Radical Absorbance Capacity (ORAC) value is considered to determine the nutrient density of the ingredient.

9.0 HOW TO USE THE CERTIFIED C.L.E.A.N. SEAL

Once the submitted documents are assessed and approved by ICIS, a manufacturer may receive a certification for CERTIFIED C.L.E.A.N.

When a product gains certification the manufacturer may:

- Use the certification imprimatur on product packaging, product advertising and product literature.
- Use the enzyme/protein/terpinoid breakdown information on the product packaging received from the CS® Tested certification analysis, in any product literature and advertising.
- Use the term “Certified Clean” or “Clean Certified”.

ICIS reserves the right to audit the manufacturer’s processes and supporting documents any time during the period in which Certification is in effect.

If the manufacturer is found to be not compliant with this standard for CERTIFIED C.L.E.A.N for certain products, the manufacturer shall immediately desist from distribution or sale of those products in packaging that includes CERTIFIED C.L.E.A.N imprimaturs.

Certification for each product must be repeated annually to carry the CERTIFIED C.L.E.A.N imprimatur on packaging, for its continued sale/distribution.

10.0 ACCREDITATION OF CERTIFYING BODIES AND CERTIFYING AUDITORS

In the Unites States, the American National Standards Institute (ANSI) accredits the organizations that certify that products and personnel meet recognized standards. The ANSI_ASQ National Accreditation Board (ANAB, http://anab.org/about-anab/) is the U.S. accreditation body for most quality management systems including ISO 22000 food safety management systems. In addition, ANSI provides laboratory accreditation for testing and calibration laboratories.

The accreditation process primarily recognizes the competence of the testing, certifying and inspecting organizations. In addition staff of these organizations can also be certified as competent individuals, assessors, auditors or lab personnel. The accreditation body must show that their staff is competent and met a standard such as ISO/IEC guide 55, or ISO/TEC 17021.

There is no current national accreditation process for Certified C.L.E.A.N., therefore this standard proposes the following to ensure that the certifiers and individual assessors are competent authorities and capable of the Certified C.L.E.A.N. Certification process.

Once an organization is accredited, its trained auditors/assessors may carry out compliance audits against the criteria herein for Certified C.L.E.A.N.

One of the key benefits of being accredited and registered with CleanFoodCertified.Org is the process of certifying Certified C.L.E.A.N. by using the multi-decision criteria of (1) Safety, (2) Minimally Processed, and (3) Bioavailability as the core criteria.

10.1 Accreditation of Raw Food Certifying Bodies and Auditors

Organizations that have been accredited by ANSI-ANAB under ISO/IEC 17025, or any other relevant conformity assessment scheme, may also become “Raw Food Certifiers”, and may be accredited by CleanFoodCertified.Org. These may include those accredited under a recognized European accreditation Board. Qualified and certified staff of such accredited organizations can become recognized certified auditors under this Raw Foods Standard.

10.1.1 Candidates for Accredited Raw Food Certifying Bodies “Raw Food Certifiers” accreditation may be conferred to organizations that have been accredited under:

- ISO 17020 Inspection Body accreditation
- ISO 17021 Management system certifying bodies’ accreditation
- ISO 17025 Calibration and test labs accreditation
- ISO 15189 Medical and clinical laboratories accreditation
- ISO Guide 34 Reference material producers accreditation
- ISO 22000 Food safety management systems
- European Cooperation for Accreditation[xi]

However, if any of the accredited bodies do not normally deal with food and food ingredients, they must demonstrate their added expertise in the area of food safety.

10.1.2 Candidates for Certified Auditors

The following staff may be eligible for certification:

10.1.2.a HARPC auditors who are trained auditors under ISO 22000 or are trained auditors acceptable for the Global Food Safety Initiative (auditors meet ISO/IEC Guide 65 or ISO/IEC 17021.)

10.1.2.b Staff of testing laboratories which are accredited through ISO 17025, or any similar ISO or European program, or the National Voluntary Laboratory Accreditation Program (NVLAP) or some other voluntary or mandatory (varies by state) accreditation program. Laboratories that are not directly involved with food must demonstrate their capability in the testing of food ingredients.

10.2 Application Process for Accreditation and Certifying Staff

To become an accredited Raw Food Certifying Body, the above candidate organizations must apply to CleanFoodCertified.Org, create an account and demonstrate their and their staff's competence as follows:

10.2.1 Access CleanFoodCertified.Org (www.CleanFoodCertified.Org) Certifier tab

10.2.2 Create a Certifier's account

10.2.3 Enter information on their current accreditation, who did the accreditation and date of accreditation

10.2.4 Enter the number and names of the trained individual auditors in the organization seeking accreditation, including their training and year of certification by relevant organization

10.2.5 Make payments according to the quoted price

10.2.6 Upload or email scanned documentation of current ISO 22000, Global Food Safety Initiative, USDA NOP, ISO 17025 or NVLAP or any other accreditation and certification

10.2.7 Proposed auditors must also acknowledge their understanding of the Raw Food Certification process as described in this draft standard

10.3 Evaluation of the application by CleanFoodCertified.Org.

10.3.1 Once the application is received, CleanFoodCertified.Org will evaluate the submitted information. If the information is satisfactory the certifying firm will be recognized as an Accredited Raw Food Certifier.

10.3.2 Each individual auditor is also evaluated by CleanFoodCertified.Org and if approved, will become a Certified Raw Food Auditor, capable to audit firms according to the raw food certification scheme.

10.4 Access to Bioavailability model

10.4.1 Once the application is approved and accepted, the accredited raw food certifier and its auditor staff will be able to submit the data for enzymatic score analysis for CS® Tested certification.

11. GUIDE TO AUDITING PROCESS FOR ACCREDITED RAW FOOD CERTIFIERS

To maintain the Certified C.L.E.A.N. certification, the food processor must agree for an audit process to make sure that the products, facilities and processing meet the multi-decision criteria of (1) Safety, (2) Minimally Processed, and (3) Bioavailability. The audit process is based on the scheme proposed by the Global Foods Safety Initiative. [xii] The steps are as follows.

11.1 The audit scheme

11.1.1 The audit starts with an administration process on agreed dates, time frames, and product testing scheme, which becomes the basis of a contract between the auditor and the food processor. The certification audits are always non-consultative. This means the auditor is not allowed to instruct or advise.

11.1.2 The audit should be scheduled on a date that is preferably within a peak production period. The audit determines a) how well a facility identifies and implements food safety controls to comply with the requirements of this standard; b) how well the facility controls the minimum processing requirements c) a testing of Bioavailability carried out via CS® Tested process.

11.1.3 The auditor assesses the safety of the product, according to section 4.0 above, reviews HARPC plans, procedures, policies, physical conditions and records and observes the implementation of the plans in the factory. These plans will be then uploaded to the CleanFoodCertified.Org website.

11.1.4 The auditor also assesses the minimum processing information as per section 5.0 above.

11.1.5 A formal report is prepared by the auditor to a format laid down by the scheme. To achieve certification, the food facility is required to correct all non-conformances and to prevent their recurrence. A time frame for corrective action is developed with the auditor.

11.1.6 CleanFoodCertified.Org will then review the evidence submitted and decides whether to accept or request a resubmission. In some cases, which may be prescribed by the scheme, a further site visit may be required to verify closure.

11.1.7 The auditor submits information on Bioavailability to the CleanFoodCertified.Org computer model. The results of this are conveyed to the auditor and to the firm.

11.1.8 The final decision on certification is not with the auditor but with RawFoddCertified.Org

11.1.9 Annual recertification is required. The rules may vary according to the scheme but typically timing will be close to the date of the initial certification audit.

GLOSSARY OF TERMS AND ACRONYMS

CS - CytoSolve - CytoSolve is a technology that provides in silico analysis of multi-combination ingredients based on molecular pathway modeling of particular biological phenomenon.

COA – Certificate of Analysis

CoPP – Certificate of Pharmaceutical Product – The certificate of pharmaceutical product (CPP or CoPP) is a certificate issued in the format recommended by the World Health Organization.

FDA – The US Food and Drug Administration

HAACP - Hazard Analysis and Risk-Based Preventive Controls Plan (HARPC) is an approach to food safety that is systematic and preventive, and is defined by FDA's Final Rule of Food Safety Modernization Act.

GMO – Genetically Modified Organism is an organism whose genome has been altered by the techniques of genetic engineering so that its DNA contains one or more genes not normally found in that species.

Global Food Safety Initiative - Established in 2000, the Global Food Safety Initiative is a business driven initiative for the continuous improvement of food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide. It is managed by the Consumer Goods Forum. There is no accreditation process but the status of recognition is achieved through a comprehensive benchmarking process. An independent third party auditor assesses a specific process against an agreed set of benchmarks.

GMP – Good Manufacturing Practices. This audit is required by the FDA for all food processing facilities

ISO 17025 – The International Standards Organization's General requirements for the competence of testing and calibration laboratories

MCDA - Multiple Criteria Decisions Analysis is a systems approach that integrates quantitative and qualitative measures

NOP – The USDA's National Organic Program

National List Ingredients: - The Organic Foods Productions Act of established a National List of Allowed and Prohibited Substances which identifies synthetic substances that may be used, and the nonsynthetic substances that cannot be used, in certified organic production and handling operations.

NON-GMO – Not a genetically modified organism.

NVLAP - National Voluntary Laboratory Accreditation Program

Product – A packaged food that, regardless of the various package sizes and shapes, has a unique mixture of ingredients (other than flavor enhancements/seasonings) that is processed in a unique, distinctive manner.

TRS 823, 863 is the World Health Organizations equivalent of the FDA GMP

USDA – United States Department of Agriculture

Appendix A - Poisonous or Toxic Raw Foods

ι) raw bitter almonds
ιι) raw cassava
ιιι) raw kidney beans
ιϖ) raw rhubarb
ϖ) raw green potatoes
ϖι) raw ackee
ϖιι) raw elderberry
ϖιιι) raw lima beans
ιξ) raw taro
ξ) raw parsnip
ξι) raw soybean
ξιι) raw fava bean
ξιιι) raw snow mushrooms (Gyromitra Montana, morels (*Morchella* sp.), hedgehog mushrooms (Hydnum repandum), oyster mushrooms (*Pleurotus* sp.) Chanterelles (*Cantharellus cibarius*, *C. formosus*, etc.) and King boletes (Boletus edulis)

Appendix B - The National List of Allowed and Prohibited Substances **(under USDA NOP)**

1. Evaluation criteria for allowed and prohibited substances (harmonized to §205.600)
2. Synthetic substances allowed for use in raw food production (§205.601)
3. Nonsynthetic substances prohibited for use in raw food production (§205.602)
4. Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "raw" or "made with raw (specified ingredients or food groups(s))" (§205.605)
5. Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "raw" (§205.606)

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "raw organic" or "made with raw organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.
Nonsynthetics allowed:

(1) Acids
- (i) Alginic
- (ii) Citric - produced by microbial fermentation of carbohydrate substances
- (iii) Lactic

(2) Bentonite
(3) Calcium carbonate
(4) Calcium chloride
(5) Colors, nonsynthetic sources only
(6) Dairy cultures
(7) Diatomaceous earth - food filtering aid only
(8) Enzymes - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria
(9) Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
(10) Kaolin
(11) Magnesium sulfate, nonsynthetic sources only
(12) Nitrogen - oil-free grades
(13) Oxygen - oil-free grades
(14) Perlite - for use only as a filter aid in food processing

(15) Potassium chloride

(16) Potassium iodide
(17) Sodium bicarbonate
(18) Sodium carbonate
(19) Waxes – nonsynthetic

(20) Cannabidiol (CBD) derived from hemp
    (i) Carnauba wax
    (ii) Wood resin
(21) Yeast - nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is
prohibited
    (i) Autolysate
    (ii) Bakers
    (iii) Brewers
    (iv) Nutritional
(v) Smoked - nonsynthetic smoke flavoring process must be documented.

Synthetics allowed:
(1) Alginates
(2) Ammonium bicarbonate - for use only as a leavening agent
(3) Ammonium carbonate - for use only as a leavening agent
(4) Ascorbic acid
(5) Calcium citrate
(6) Calcium hydroxide
(7) Calcium phosphates (monobasic, dibasic, and tribasic)
(8) Carbon dioxide
(9) Chlorine materials - disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
    (i) Calcium hypochlorite
    (ii) Chlorine dioxide
    (iii) Sodium hypochlorite
(10) Ethylene - allowed for postharvest ripening of tropical fruit
(11) Ferrous sulfate - for iron enrichment or fortification of foods when required by regulation or recommended (independent organization)
(12) Glycerides (mono and di) - for use only in drum drying of food
(13) Glycerin - produced by hydrolysis of fats and oils
(14) Hydrogen peroxide
(15) Lecithin - bleached
(16) Magnesium carbonate - for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”
(17) Magnesium chloride - derived from sea water
(18) Magnesium stearate - for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”
(19) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods
(20) Ozone
(21) Pectin (low-methoxy)
(22) Phosphoric acid - cleaning of food-contact surfaces and equipment only

(23) Potassium acid tartrate
(24) Potassium tartrate made from tartaric acid
(25) Potassium carbonate
(26) Potassium citrate
(27) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables
(28) Potassium iodide - for use only in agricultural products labeled "made with organic specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"
(29) Potassium phosphate - for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic"
(30) Silicon dioxide
(31) Sodium citrate
(32) Sodium hydroxide - prohibited for use in lye peeling of fruits and vegetables
(33) Sodium phosphates - for use only in dairy foods
(34) Sulfur dioxide - for use only in wine labeled "made with organic grapes," Provided, that, total sulfite concentration does not exceed 100 ppm.
(35) Tocopherols - derived from vegetable oil when rosemary extracts are not a suitable alternative
(36) Xanthan gum

Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with organic ingredients.

The following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(a) Cornstarch (native)
(b) Gums - water extracted only (arabic, guar, locust bean, carob bean)
(c) Kelp - for use only as a thickener and dietary supplement
(d) Lecithin – unbleached
(e) Pectin (high-methoxy)

ENDNOTE REFERENCES

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