Global Harmonization Initiative
Advancing science-based food safety law and trade

Food Preservation Technologies

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Mission

- Collect and make available information about existing international regulations on novel thermal and non-thermal technologies
- Exchange and summarize knowledge and to set up of database of applications in industry worldwide in order to accelerate and clarify the path for the approval/validation of new processes
- It is envisioned that WG recommendations will lead to harmonization of relevant international requirements.

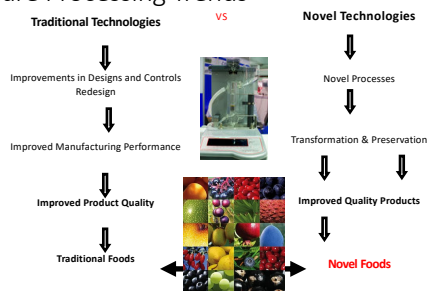
Headlines & Technology Trend lines

- Natural
- Raw
- Organic
- Fresh
- Vegan

- Extended Shelf Life
- Increased level of Safety
- Novel Processing Technologies
  - More than 30 solutions
  - HPP is emerged
  - PEF is emerged
  - UV LIGHT is emerged

Juices
- Cold pressed/HPP
- Cold pressed/LIGHT?

Future Processing Trends



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Key Drivers

- Freshness & Convenience & Less preserved
- Enhanced Safety and Extended Shelf-Life
  - Pathogen reduction in fresh produce
  - Listeria post-lethality treatments
- Heat labile functional ingredients
- Engineering functional ingredients delivery of healthy foods
- Lower carbon footprint and reduce water volume used in heat transfer processes
- Need for sound regulatory policy
  - U.S., Canada, EU

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Global Regulations

NOVEL FOODS
- European Union
- United Kingdom
- New Zealand/Australia
- Canada
- China

NO DEFINITION OR OTHER TERMS
- USA
- Japan
- India

Thermal Technologies

Traditional (9)

- Canning – in package retorting
- Aseptic Sterilization
  Package in sterile conditions-Cool
- Pasteurize - Package – Cool :
  "Hot-Fill" Technique
- Pasteurize - Cool – Package :
  "Cold-Fill" Technique
- Package - Pasteurize - Cool :
  "Sous vide' Technique

Novel/Emerging

- Pressure + Heat (8)
- Radiative or Microwave dielectric (8)
- High frequency (HF) or Radio Frequency (RF) dielectric
- Infrared (6-7)
- Ohmic heating/Conductive (5-6)

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Knowledge in Thermal Processing

- Established organism of public health concern
- Understood the destruction kinetics/mathematics necessary to evaluate a treatment
- Developed knowledge how products heat for given processing systems
- Generated principles on the relationships between the organism of public health concern and spoilage
- Ability to express a complicated process delivery in simple "Lethality" terms so as to understand the equivalent safety of different processing systems

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Non-thermal Technologies

Emerged

- Irradiation (9)
- High hydrostatic pressure (8-9)
- Filtration (9)
- Ozone (8-9)

Emerging

- Pulsed Electric Fields (6-7)
- UV light (6)
- Pressure and CO_2 (6)

Under development

- Cold Plasma (3-4)
- Electrolyzed water (5-6)
- Sonication (5)
- Low dose e-beams (6)

Scale 1 to 10

Gaps in Novel Food Preservation

- Process equivalency
- Target organisms of concerns has to be determined along with the surrogates
- Detailed knowledge of microbial dose-response behavior
- Complete representation of the distribution of the lethal agent and velocity fields for development of an accurate process models
- Chemical safety
- Process uniformity
- Process monitoring, verification and validation

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Challenges of Novel Food Processing

Safety Equivalence

Traditional Foods VS Novel Foods

Traditional Process VS Novel Process

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Novel Foods in EU

Regulated by EC 258/97
Term: Novel Foods

- Foods and food ingredients with a new or intentionally modified primary molecular structure
- Foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae
- Foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating and breeding practices and having a history of safe food use
- Foods and food ingredients to which has been applied a production process not currently used, where that process
  - gives rise to significant changes in the composition or structure of the foods or food ingredients
  - which affect their nutritional value, metabolism or level of undesirable substances

Australia/New Zealand

- Terms: Non-traditional Foods
  Novel Foods
  Regulated by Food Standard: FSANZ
  1.5.1 – Novel Foods

Non-Traditional Foods - a food which does not have a history of significant human consumption by the broad community

Novel Foods - a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use taking into account -

(a) the composition or structure of the product; or
(b) levels of undesirable substances in the product; or
(c) known potential for adverse effects in humans; or
(d) traditional preparation and cooking methods; or
(e) patterns and levels of consumption of the product.

China

- Terms: Novel Foods
  - Animals, plants and microorganisms that are not traditionally consumed in China;
  - Raw food materials that are derived form animals, plants and m/o and are not traditionally consumed in China
  - New varieties of m/o that are used during food processing
  - Raw food materials the original compostion or structures of which are changed by the adoption of new techniques during production

USA

No definition can not be found

- US FDA considers food ingredients as novel that have not been previously used
- New dietary compounds (NDI)
- As food additives under existing law, the principal law being the Federal Food, Drug and Cosmetic Act.
- The 'Generally Recognised as Safe' or GRAS concept is the bench mark by which all foods, including novel foods, are assessed.
- GRAS substances are: substances used before 1958 (excluding prior sanctioned food ingredients); and substances for which there is scientific evidence of safety as determined by competent experts and by published and available safety information.

US Approvals of Novel Processes

- 2001, Code 21 CFR Part 179.39 was published to improve the safety of fresh juice products: Source of UV radiation (LPM at 254 nm) defined as a food additive
- 2004, USDA has approved High Hydrostatic Pressure as an intervention method for *Listeria* contaminated pre-packed ready-to-eat (RTE) meat products
- 2008, 73 FR 49593 The FDA published a final rule that allows the use of irradiation for fresh iceberg lettuce and fresh spinach
- 2009, the US FDA approved a petition for the commercial use of Pressure Assisted Thermal Sterilization process (PATS) for application in the production of LAF
- 2010, US FDA first time approved novel sterilization processing using 915 MHz microwave energy (MATS) for producing pre-packaged, LAF

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Government Agencies

- Canadian Food Inspection Agency (CFIA)
- Health Canada (HC)
- Public Health Agency of Canada (PHAC)
- Agriculture and AgriFood Canada (AAFC)

- 20 Research Centers
- Guelph Food Research Center
  - food safety and quality
  - development of functional foods with health-giving properties

Health Canada Santé Canada

Novel Foods Regulations in Canada

- HC assesses the safety of all GM and other novel foods proposed for sale in Canada
- Companies are required to submit detailed scientific data for review and approval by HC, before such foods can be sold
  - Food and Drugs Act and Regulations
  - Division 28: Novel Foods
    - Notification prior sale or advertising
- Guidelines for the Safety Assessment of Novel Foods are available (1994)

Novel Foods Definition: Canada

Foods that meet ANY of these 3 definitions would require a pre-market notification

1. *Products that do not have a history of safe use as a food*
2. *Foods resulting from a process not previously used for food that causes the food to undergo a major change*
3. *Foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods*

1. History of Safe Use

- A food is considered to have a history of safe use if:
  - part of the diet for a number of generations in a large, genetically diverse human population
  - used in ways and at levels that are similar to those in the Canadian market
- A history of use in a jurisdiction with a similar food safety system would increase the level of confidence

2. Novel Process

- Some processes applied to ***foods*** or ***food ingredients*** may result in the generation of foods which would be considered novel in relation to traditional counterparts.
  - *new heat processing techniques; new packaging technologies; the use of ultraviolet light*
- The application of new processes which cause a food to undergo a major change would trigger the requirement to notify Health Canada

Novel Process Resulting a Major Change

- **A major change** is defined in Division 28 of the Regulations as a change in a food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the food outside the accepted limits of natural variations for that food with regard to:
  - composition
  - structure
  - nutritional quality of the food or its generally recognized physiological effects
  - the manner in which the food is metabolized in the body
  - microbiological safety
  - chemical safety or the safe use of the food

Who does What?

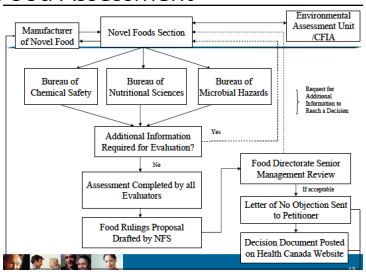
Health Canada

- Evaluation for human Consumption
  - Bureau of Chemical Safety
  - Bureau of Nutritional Science
  - Bureau of Microbial Hazards

CFIA

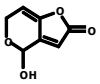
- Environmental Evaluation
  - Plant Biosafety Office
  - Plant and Biotechnology Environmental
- Release Assessment Unit
  - Animal Feed Evaluation
  - Animal Feed Division

Novel Food Assessment



Risk-based Assessment of Safety of Novel Foods

- Details of novel process
- Dietary Exposure
- History of organism
- Nutritional considerations
- Toxicology considerations
- Allergenicity considerations
- Chemical considerations
  - Process derived chemical hazards
  - Furans
  - Products of lipid oxidation



Approved to Date

208 novel foods since 1994

57 products with "no history of safe use"
- Phytosterols
- Shell eggs with lutein

13 novel processes
- High Pressure Processed Food Products
- UV treated Apple Cider
- Other processing technologies

138 products of genetic modification
- Round-up Ready Corn, Clearfield Rice
- Soybean with increased yield

Health Canada Santé Canada

Novel Foods Decisions for HPP (9)

Product	Pressure	Holding Cycle Time (min)	Maximum Treatment Length (min)	Purpose
Apple sauce and apple sauce/fruit blends	550 MPa	1	1	Alternative to thermal processing for shelf-life extension
Ready-to-eat meats and poultry products	600 MPa	3	27	Post lethality treatment to reduce *Listeria monocytogenes*
Ready-to-eat meat containing entrees, meat containing salads and meat products	600 MPa	3	3	Post-lethality treatment for shelf-life extension
Avocado pulp, guacamole and tomato based salsa	600 MPa	3	9	Shelf-life extension
Raw ground beef	600 MPa	1	3	Reduction of *E coli* O157:H7 and shelf-life extension
Fruit and vegetable smoothies	593 MPa	2	2	Shelf-life extension
Fruit and vegetable based juices	600 MPa	2	9	Shelf-life extension
Raw Fruit Juices	550 MPa	1	9	Shelf-life extension
Egg Salad, Egg Dips, and Egg Spreads	600 MPa	2	27	Shelf-life extension

Novelty Determination

Health Canada Santé Canada

Guidance for Industry on Novelty Determination of High Pressure Processing (HPP)-Treated Food Products (June 2014)

- Product listed in the table are no longer NOVEL
- Any food not previously treated with HPP or food subjected to new set of conditions or with different purpose is considered NOVEL

Health Canada Position

- Foods and food ingredients treated with HPP sold in the Canadian market since 2004
- Health Canada has assessed a number of HPP-treated foods and food ingredients
  - Ready-To-Eat meats, raw meats, fruit and vegetable-based juices/smoothies, egg products and other spreads, etc.) under a range of pressures (80,000-87,000 psi) and times (1-27 min).
- Based on the number of HPP-related assessments conducted, the scientific literature currently available regarding HPP and the breadth of food products that are known to be treated with HPP
- The position of Health Canada (December 2016)
  - **HPP is no longer considered a novel process**
- Food products treated with HPP
  - **no longer be considered novel foods**
  - no longer subject to pre-notification

HC Guidance on food products treated with HPP

- HPP-treated foods sold in Canada must comply with all applicable legislative and regulatory requirements
  - the sensitivity of microorganism(s) of concern to HPP,
  - the intended purpose of the HPP treatment,
  - the characteristics of the food product,
  - the storage conditions of the end product,
  - the potential for the introduction of food safety hazards due to shelf-life extension resulting from HPP
  - provide validation information for HPP processes.

Validation of HPP processes

Purpose	Validated Maximum Pressures (psi/MPa)	Validated Maximum Time at 87,000 psi (min)	Validation Requirements
Shelf-life extension	87 000/600	27	Addition validation is not required unless a food safety hazard(s) may be introduced by the extended shelf life.
Pathogen reduction where HPP treatment is not a critical control point	87 000/600	27	Additional validation is not required unless the post-lethality treatment is associated with re-classification of the product to a lower risk level
Other technical processes (e.g. shell removal of crustaceans)	87 000/600	27	Additional validation is not required.
Pathogen reduction where HPP treatment is a critical control point	None	None	Validation is required. Consult with CFIA.
Reconditioning	None	None	Validation is required. Consult with CFIA.

High Pressure Processing for Ready-to-Eat Meat Products

- HPP is an approved post-lethality, post-packaging intervention step for RTE meats for the control of *Listeria* spp. This process may be used as an additional step to enhance the microbiological safety of these products.

- **Process Parameters for High Pressure Processing**
- The chamber must be pressurized to 87,000 PSI or 600 MPa
- The pressure must be maintained for 3 - 9 minutes
- A maximum of three cycles is permitted.
- The pressure is released and the treated containers are packed and ready for shipping.

- **Packaging Material for Use in High Pressure Processing**
- The operator is required to ensure that any packaging material that is used in the sale of food products will not impart any undesirable substance to the meat product, either chemically, physically or microbiologically and must protect them sufficiently to avoid contamination.

Documenting information on HPP-treated food products

- Description of the food item
- Description of the HPP treatment being applied
  - pressure applied, holding time, number of cycles, temperature
- Description of the intended purpose of the HPP treatment shelf-life extension, pathogen reduction, critical control point (CCP), post-lethality, re-conditioning

- Justification or data demonstrating that the HPP treatment is effective for its intended purpose and that the final product meets all food safety requirements.
  - process schedules, shelf-life studies, manufacturer's declarations for packaging materials etc.

UV light

Health Canada Santé Canada

- HC considers ULTRAVIOLET **LIGHT** treated foods as Novel Foods

- Companies are required to submit detailed scientific data for review and approval by HC, before such foods can be sold

Health Canada - Novel Food Decisions

- Ultraviolet light treatment of apple juice/cider using the CiderSure 3500, (Moore Orchards, July 15, 2003)

- Health Canada has notified Moore Orchards that it has no objection to the sale of unpasteurized and unfermented apple juice and cider products which have been treated with the CiderSure 3500 Ultraviolet (UV) light unit.

- The CiderSure 3500 UV light unit has been developed to treat apple juice/cider with UV light to reduce the levels of microbial pathogens in juice products.

- The intent of the CiderSure 3500 is specifically to reduce the levels of *Escherichia coli* 0157:H7

Laminar and turbulent flow: CiderSure

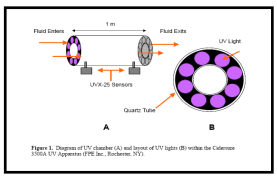


Figure 1. Diagram of UV chamber (A) and layout of UV lights (B) within the Ciderzure 3500A UV Apparatus (FPE Inc., Rochester, NY).

CIDERSURE MODEL	GPH
2500	25-30
3500	100-120
3500B	160-200
5500	250-300
6500	500-600

Approved by Health Canada in turbulent regime for treatment apple juice/cider

New applications of UV

- UV for a variety of cold pressed juices
  - To extend shelf-life
  - To comply with HC requirements
- In progress
  - Effect of UV dose on juice composition
  - Nutrients content
  - Furan formation

Novel Feeds

- Novel feeds are feeds composed of or derived from microorganisms, plants or animal sources that:
  - are not approved as livestock feed in Canada
  - and/or contain a novel trait
- Novel feeds include
  - microbial products (e.g. forage inoculants, fermentation products)
  - plants with novel traits, and plants with no history of use as feed, and
  - products/by-products of biotechnology-derived animals.

CFIA Safety Requirements

- The CFIA evaluates and regulates all feed ingredients, including novel feed the same manner.
- Novel feeds must be assessed by the Feed Section before they can be used as livestock feed in Canada.
- Any feed ingredient that is new (i.e., is not already listed in Schedules IV or V of the Feeds Regulations), or has been modified such that it differs significantly from a conventional ingredient, is required to undergo a pre-market assessment and approval.
- This assessment considers the safety
  - feed to livestock
  - humans via worker/by-stander exposure and consumption of animal products
  - environment

Assessment Principles

- Case-by-case basis
- Comparative Approach
- Scientific rationale
- Data quality
- Presentation of information
- Harmonization With Other Regulatory Parties

Food Irradiation in Canada

- Regulated by CFIA
- *Listeria* outbreaks
- February 2017, amendments to FI
  - Fresh raw beef
    - Gamma, e-beam, X-rays
    - Dose 1.0 - 4.5 kGy
    - To reduce microbial load including pathogens
  - Frozen raw beef
    - Gamma, e-beam, X-rays
    - Dose 1.5 - 7.0 kGy
    - To reduce microbial load including pathogens

CFIA reasoning

- Scientific evidence supports the safety and efficacy of irradiation
- IR technology's potential to increase food safety and improve public health (reduce potential for foodborne illness);
- Other irradiated foods are already permitted on the market
- FI facilities are currently in place in Canada (straightforward implementation)
- Endorsed by the World Health Organization and the Food and Agriculture Organization of the United Nations
- Internationally, irradiation is already permitted for various products, including beef
- Regulatory proposal aligns with U.S. regulations
- FIR provides an additional choice for consumers
- Labelling will allow informed choice and potentially increase public confidence in the food supply.

GHI Consensus Document on Food Irradiation

Discordant international regulations of food irradiation are a public health impediment and a barrier to global trade

October 2018
Working Group Food Preservation Technologies

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Existing international irradiation regulations

North America
Central and South America
European Union
Russia
Oceania
Asia
Africa General

Discordant doses allowances
Discordant labelling of foods and food ingredients

- GHI also supports international recommendations for comprehensive integrated food safety programmes, as foundations for allowing and supporting the use of ionizing radiation in food processing operations.
- Current labelling of irradiated foods is incorrectly but frequently seen as a safety warning. Due to the consumer misperceptions, the current label is seen as misleading and lacks transparency.
- Based on the long history of use, global geography of irradiated foods (both labelled and unlabelled) and the needs of international trade, GHI recommends that all foods treated below the doses that will not compromise sensory quality and are deemed wholesome, should bear no mandatory label or a label that will be educative rather than misleading, encouraging consumer purchase of safe and wholesome foods.