



E. Date: January 18/2021

## Declarations of Compliance

### HACCP and FOOD SAFETY Compliance

Kenney & Ross Limited have implemented and maintained quality control procedures to ensure the safety of our products. HACCP and Food Safety are part of our Quality Management Program approved and registered with the Canadian Food Inspection Agency under the Safe Food for Canadians Act for Food Grade Fish Gelatin and Collagen products produced. Kenney & Ross Limited CFIA Registration No. 8M7DDFCB.

### Good Manufacturing Practices (GMP)

Kenney & Ross Limited Quality Management Program incorporates Health Canada and Internationally recognized Good Manufacturing Practices in the process to produce Food Grade Fish Gelatin, Hydrolyzed Fish Collagen, and Technical Grade Gelatin. We provide adequate GMP, sanitation and operational procedure training to employees and ensure consistent product quality with no food safety risks. Every lot/batch of Finished Products is packaged using approved materials, tested by Third-party Laboratories, and released using supporting documentation. We continually strive to maintain and exceed domestic, and internationally recognized GMP standards.

### ISO 9001:2015

Kenney & Ross Limited is committed to maintaining ISO 9001:2015 Certification for our Quality Management Systems. The certificate number is CERT-0139324 with SAI Global.

### International Compendium Standards

Kenney & Ross Limited Fish Gelatin and Hydrolyzed Fish Collagen meet the requirements of the US, EU, JP, Chinese Pharmacopoeia and Food Chemical Codex. Our Products also meet the following:

- EU Regulations 852/2004, 853/2004, 854/2004, 178/2002, and 92/118.
- China Gelatin GB 6783-2013 and Collagen GB 31645-2018 Standards.

### European Approval

Kenney & Ross Limited is an approved facility to export both Food Grade Fish Gelatin and Hydrolyzed Fish Collagen to the European Union Countries under Registration No. 3738.



## Sustainability of Resources

Kenney & Ross Limited is committed to providing customers with a consistent supply of Fish Gelatin and Fish Collagen products that are produced by raw materials sourced from well-managed fisheries focusing on sustainable practices.

We certify that the Fish Gelatin and Hydrolyzed Fish Collagen are manufactured in Canada by Kenney & Ross Limited from the skins of Wild, Deep-Sea, Cold-Water Kosher Fish Species, such as Atlantic/ Pacific Cod, Haddock, and Pollock.

All skins are obtained from fish processors filleting fish for human consumption as a by-product in that industry.

The fish processors and collectors are in Canada, the United States, Iceland, the Faroe Islands, Denmark, Norway, and Russia. Skins are obtained from major water bodies when quotas allow fishing, such as the Atlantic Ocean, Pacific Ocean, Bering Sea, Gulf of Alaska North Sea, Norwegian Sea, Greenland Sea, and Barents Sea.

To meet a wide range of definitions for sustainability we ensure our fish skins are Wild caught and sourced so that legislation, regulations and/or quotas are established in each Country.

Canada has one of the most advanced programs in the world for monitoring, control, and enforcement of fisheries. Key elements of this program include electronic catch monitoring, license requirements for fish harvesters, dockside monitoring services, independent onboard observers to monitor catch, electronic monitoring systems for fishing vessels and gear, legislation and regulations that set out the rules for the fishing industries, aerial and at-sea patrols to monitor fishing vessel activity within and beyond Canada's 200-mile limit.

The United States National Oceanic and Atmospheric Administration Fisheries Department of US Commerce assesses that "marine wild captured fisheries in the United States are scientifically monitored, regionally managed, and enforced under ten national standards of sustainability through the Magnuson-Stevens Fishery Conservation and Management Act – exceeding the international standards for eco-labelling of Seafood."

Iceland has taken a leading role in managing its fisheries, focusing on sustainable practices. The Icelandic fisheries system was developed following international law and the United Nations Food and Agriculture Organization's Code of Conduct for Responsible Fisheries.

In Europe, the Common Fishery Policy (CFP) is the fisheries policy of the European Union (EU). It sets quotas for which member states can catch each type of fish, as well as encourages the fishing industry through various market interventions.





Due to many different definitions of Sustainability, Kenney & Ross Limited does not seek Third Party Certifications.

## Certification of Raw Materials

Kenney & Ross Limited Certify that all Fish Gelatin is manufactured from the skins of wild, deep sea, cold water Kosher fish species such as:

<u>Common Name</u>	<u>Scientific Name</u>
Atlantic Cod	Gadus morhua
Atlantic haddock	Melanogrammus aeglefinus
Atlantic Pollock	Pollachius virens
Hake	Merluccius bilinearis
Red Fish	Sebastes fasciatus
Pacific Cod	Gadus macrocephalus
Alaskan Pollock	Gadus chalcogrammus

Kenney & Ross Limited certify that all Fish Collagen is manufactured from the skins of wild, deep-sea, cold-water Kosher fish species such as:

<u>Common Name</u>	<u>Scientific Name</u>
Atlantic Cod	Gadus morhua
Atlantic haddock	Melanogrammus aeglefinus
Atlantic Pollock	Pollachius virens

These skins are obtained from registered fish processing facilities approved for filleting fish for human consumption.

The Fish Processors are in Canada, the United States, Iceland, the Faroe Islands, Denmark, Norway, and Russia. The skins are obtained from the following major water bodies through approved quotas:

Atlantic Ocean	North Sea
Pacific Ocean	Norwegian Sea
Bering Sea	Greenland Sea
Gulf of Alaska	Barents Sea



## **Raw Materials Origin**

Kenney & Ross Limited raw materials are fish skins sourced from wild-caught fish only, and free from pork, bovine, other animals, or their derivatives. Our facility and processes are designed to process fish skins to produce gelatin and collagen products which are certified by the Orthodox Union, IFANCA and Halal Montreal to meet customers' requirements.

## **Kosher Statement**

Kenney & Ross Limited Fish Gelatin and Hydrolyzed Fish Collagen meet the requirements of Kosher and are certified by the Orthodox Union through the Union of Orthodox Jewish Congregations of America in New York, USA. Certificates are available upon request or provided with the shipment as per the shipping agreement.

## **Halal Statement**

Kenney & Ross Limited Fish Gelatin and Hydrolyzed Fish Collagen meet the requirements of Halal and are certified by both the Islamic Food and Nutrition Council of America (IFANCA) and Halal Montreal Certification Authority. Certificates are available upon request or provided with the shipment as per the shipping agreement.

## **Allergen Statement**

The raw materials for manufacturing fish gelatin and hydrolyzed fish collagen are fish skins obtained from fish processing plants where fishery products are prepared for human consumption. Each stage of the manufacturing process is rigorously controlled to ensure product purity and quality.

The major allergen in fish, parvalbumin, is known to cause allergic reactions in individuals with an allergy to fish. It is a water-soluble protein located in the flesh and skin of fish. Kenney & Ross Limited's process of manufacturing gelatin/collagen involves washing the fish skins followed by hydrolysis, and purification to remove the allergen to insignificant amounts below commercial testing detection limit >1ppm.

The allergenic potential of commercial food-grade fish gelatin was evaluated in an oral challenge study in the literature<sup>a</sup>. "The results from this randomized, double-blind, placebo-controlled oral challenge clinical study, as well as the rigorous removal of potential allergens during the fish gelatin production provide assurance that allergenic risks are low."

*a. Hansen TK, Poulsen LK, Skov PS, Hefle SL, Hlywka JJ, Taylor SL, Bindslev-Jensen U, Bindslev-Jensen C, A randomized, double-blinded, placebo-controlled oral challenge study to evaluate*



*the allergenicity of commercial, food-grade fish gelatin. Food and Chemical Toxicology 42(2004), 2037-2044*

We certify that none of the following allergic ingredients is used on Kenney & Ross Limited equipment or in the manufacturing of Fish Gelatin and Hydrolyzed Fish Collagen.

- Milk.
- Eggs.
- Crustacean shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, walnuts, pecans)
- Peanuts.
- Wheat.
- Soy.
- Mustard
- Sesame seeds
- Sulphites

Kenney & Ross Limited's analysis for Fish Allergens (parvalbumin) uses an Enzyme-Linked Immunosorbent Assay (ELISA) method that has a detection limit of  $\geq 0.02$  ppm vs commercial tests' detection limit of  $>1$  ppm. Our products are guaranteed to be significantly  $< 1$  ppm parvalbumin.

### **BSE and TSE Certification**

We certify that all Fish Gelatin and Hydrolyzed Fish Collagen are derived from the skin of fish. All skins are received at Kenney & Ross from food fish processing plants that do not process any ruminant material or other materials of concern. Concerns related to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) are restricted to raw material from animal species other than fish.

EU Guidance 2004/C 24/03 lists TSE diseases for animals of concern as: bovine spongiform encephalopathy in cattle, scrapie in sheep and goats, chronic wasting disease (CWD) in cervids (deer and elk), transmissible mink encephalopathy (TME) in farm-raised mink, feline spongiform encephalopathy (FSE) in Felidae (cats), and spongiform encephalopathy of exotic ungulates in zoos.

The **European Pharmacopoeia** Chapter 5.2.8 and EMEA/410/01 pertain to animal species that are unrelated to fish and are not applicable.

Kenney & Ross does not manufacture Fish Gelatin and Hydrolyzed Fish Collagen from sources other than fish, so there is no possibility of contact with materials of concern during any stage of the fish gelatin or collagen production process.





## **Heavy Metal Statement**

Kenney & Ross Limited ensures that all Fish Gelatin and Hydrolyzed Fish Collagen meet Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. All Heavy metals (lead, cadmium, mercury, inorganic tin) meet the European Standard.

## **Dioxin Certification**

Kenney & Ross, Limited. is the sole manufacturer of Dried Fish Gelatin and Hydrolyzed Fish Collagen. We certify that we test random samples of the Fish Gelatin and Collagen each year to verify that they do not exceed 0.5 picograms of dioxin per gram. To put this quantity in perspective, the limit in EU regulations for Fish Oil for human consumption is 2 picograms/gram, and the limit for fresh fish is 4 picograms/gram. A Picogram is 0.000 000 000 001 grams.

We also certify that PCBs are oil-soluble chemicals rather than water-soluble. If they were present, they would only reside in the fish oil portion of our Fish Gelatin and Collagen. Additionally, the fish skins Kenney & Ross used are from wild, deep-sea species that have very little risk of contamination with PCBs. Our Gelatin and Collagen products may have trace amounts of oil left after processing and the presence of PCBs, if any, will be insignificant.

The EU previously required certification of no preservatives in the Gelatin and Hydrolyzed Fish Collagen. K&R confirmed with testing that there were no preservatives (<1 ppm) in the products.

## **Declaration of Contamination Free**

Kenney & Ross Limited certifies that Fish Gelatin, Hydrolyzed Fish Collagen, and the raw materials used to manufacture our products are free from the following contaminants:

- Free from Genetically Modified Organisms (GMOs)
- Free of ingredients – All natural, pure, organic – Declared as natural as described in the US Code of Federal Regulations 21 CFR 101.22a3 and EU Flavor Directive 88/388 EEC Article 9a (2).
- Free from NanoTech
- Free from hormones
- Free from toxic, drastic, narcotic, and psychotropic substances, as well as doping substances or other substances on the World Anti-Doping Agency List (WADA).
- Free from pesticide contamination. Compliance with Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin including amendments for the Commission Regulations (EU) 2023/466 & (EU) 2023/710, and



Regulation (EC) 1881/2006 setting maximum levels of certain contaminants in foodstuffs. No pesticides are used at the manufacturing facility.

- Free of Gluten
- Free of Glyphosate
- Free from irradiation of Ethylene Oxide treated (ETO)
- Free from Melamine residue
- Free from viruses, diseases and/or pathogens. Wild Caught Fish are not prone to transmissible viruses and diseases to humans.
- Free from Residual solvents – No Class 1 or Class 2 residual solvents are being used in the manufacture of Fish Gelatin and Fish Collagen. All products will comply with the 0.5% limit for Class 3 residual solvents as specified in Chapter 5.4 of the European Pharmacopeia and General 467 of the US Pharmacopeia. Fish Gelatin and Fish Collagen also comply with the CPMP guideline for residual solvents (CPMP/ICH/283/95 amended by CPMP/ICH/194/00)
- Free from Mycotoxins
- Free from Aflatoxins
- Free from Latex (Non-latex gloves used in the packaging of product)
- Free from Antibiotics
- Free from Aspartame
- Free from Benzoate
- Free from Hydroxybenzoic Acid Esters
- Free from Potassium & Sorbic Acid salts
- Free from animal derivatives used in manufacturing and/or deionization.
- Free from synthetic solvents and synthetics NOT listed under 7CFR205.605.
- Free from X-ray and/or radiant rays
- Free from Radiological contamination or treatment
- Free from Sulphur Dioxide, Sulphites, or any other reducing agents

### **Proposition 65 Certification**

Kenney & Ross Limited Fish Gelatin and Hydrolyzed Fish Collagen meet the requirements of California Proposition 65.

### **Shelf-Life Stability Statement**

Kenney & Ross Limited Fish Gelatin and Hydrolyzed Fish Collagen have a shelf life of 36 months from the production date. Shelf-Life Samples are stored at ambient temperatures and evaluated at a minimum of 1 year past the expiry date. There have been no significant changes in product characteristics, safety, and quality.



# KENNEY & ROSS LIMITED

CONFIDENTIAL

6493 SHORE ROAD, PORT SAXON NOVA SCOTIA CANADA B0T 1W0

Phone (902) 637-2616

www.kenneyandross.com

## REACH Declaration

Kenney & Ross Limited Fish Gelatin and Hydrolyzed Fish Collagen are exempt from REACH regulations. The regulation (EC) No. 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), does not apply to gelatin/collagen and their hydrolysates as they are natural polymers and/or chemically modified natural polymers. The amino acids are regarded as non-isolated intermediates and therefore do not have to be registered, obligations according to Article 2, paragraph 9 of the REACH Regulation.

## Origin Declaration

Kenney & Ross Limited is the manufacturer and exporter of Fish Gelatin and Hydrolyzed Fish Collagen produced in the facility located at:

6493 Shore Road  
Port Saxon, Nova Scotia B0T 1W0  
Canada

Health Canada Registration # 302611  
Canadian Food Inspection Agency Registration #8M7DDFCB  
EU Approval No.#3738  
EU Technical Grade Gelatin Registration # ABP-76  
FDA DUNS 200294635  
Nova Scotia Fish Processor License # PL2554  
The information above is certified as true and correct.

**Declaration of Compliance is valid for 1 year.**

Jody Crook, Vice President & General Manager

Date: Nov. 22, 2023