

**PETITION BEFORE THE
UNITED STATES DEPARTMENT OF AGRICULTURE (USDA),
FOOD SAFETY INSPECTION SERVICE (FSIS)**

**THE HUMANE SOCIETY OF
THE UNITED STATES,**

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Washington, D.C. 20037,

FARM SANCTUARY, Inc.

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Petitioners,

Filed With:

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in his official capacity as
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OFFICE OF THE EXECUTIVE
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Alfred V. Almanza,)
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PETITION FOR RULEMAKING

I. Introduction

This petition is submitted on behalf of the Humane Society of the United States (“HSUS”), Farm Sanctuary, Animal Legal Defense Fund (“ALDF”), NYU Student Animal Legal Defense Fund (“NYU SALDF”), Jessica Gorman, Doris Booth, Daniel Stahlie, (hereafter “petitioners”) requesting rulemaking by the United States Department of Agriculture and its Food Safety and Inspection Service (collectively “USDA” or “Agency”) to prohibit the introduction of force-fed foie gras into the human food supply. Pursuant to the Poultry Products Inspection Act (“PPIA”), its implementing regulations and agency policy, the USDA must inspect poultry carcasses and products and shall condemn all carcasses or products found to be adulterated. *See* 21 U.S.C. § 455 (2007).

As described herein, force-fed foie gras is a diseased poultry product made from fatty, degenerated duck or goose liver. The disease is caused through the process of force feeding or “gavage” which involves inserting a long tube down the throat of a bird, two to three times a day, and forcing a pre-measured amount of food into the bird’s digestive system through the tube. After approximately 2-4 weeks of force feeding, and once the fatty, diseased liver has reached maximum size, the bird is slaughtered shortly before it would die from its diseased state.¹

¹ The process of force feeding is completely unnecessary for the production of foie gras. A Spanish farmer, Eduardo De Sousa, produces foie gras without force-feeding. Mr. De

According to a recent study published in the Proceedings of the National Academy of Sciences, the consumption of foie gras may trigger the onset of Secondary Amyloidosis in certain people, including those with inflammatory diseases such as rheumatoid arthritis, and thus is potentially hazardous to human and public health.

Therefore, petitioners request that the USDA initiate rulemaking to exclude force-fed foie gras from the food supply as an adulterated and diseased product that is “unsound, unhealthful, unwholesome, or otherwise unfit for human food.” 21 U.S.C. 453(g)(3) (2007).²

II. Interests of the Petitioners

Petitioner The HSUS is a non-profit charitable organization that promotes the protection of all animals. It maintains its headquarters in Washington DC, and is the largest animal protection organization in the United States, with more than ten million members and constituents. The HSUS’ mission is to foster the humane treatment of all animals through several program initiatives: it actively advocates against practices that injure or abuse farm animals, and it promotes the humane slaughter of animals that will enter the food chain.

The HSUS offers information regarding the inhumane treatment of animals on a wide spectrum of topics including: the effects of intensive confinement and transport of

Sousa’s farm has approximately 2,000 geese who gorge themselves on figs, acorns, lupins and olives left in piles around his 30-acre farm. Mr De Sousa’s foie gras product has won the Coup de Coeur, a prestigious award from the Paris International Food Salon. See Telegraph.co.uk, *At last, guilt-free foie gras*, (March 11, 2007), available at <http://www.telegraph.co.uk/wine/main.jhtml?xml=/wine/2007/11/03/edfoie103.xml> (last visited Nov. 17, 2007).

² As used herein, the term “force-fed foie gras” shall refer to the liver of a duck or goose that has been specially fattened, that is, produced using a high volume of any specialized diet delivered by force feeding or “gavage.”

farm animals, public health problems associated with the practice of slaughtering diseased animals, and other threats caused by current industrial farming and slaughter practices. Some HSUS members and staff consume products that come from U.S. slaughter facilities -- including ducks and geese -- as well as other poultry and poultry products. These consumers have a strong personal interest in ensuring that all animals raised for human use are treated with compassion, and that the processing of such animal products comport with the PPIA, its implementing regulations, and the Agency's declaration mandating the condemnation of adulterated, fatty, degenerated livers.

Petitioner Farm Sanctuary is a non-profit charitable organization dedicated to protecting animals raised in the "food industry." It maintains its headquarters in Watkins Glen, NY and is the leading farm animal protection organization and sheltering network in the United States. Farm Sanctuary's mission is to protect animals subjected to the cruelest agri-business practices through investigations, legal and legislative actions, public education, and rescue efforts. Farm Sanctuary provides sanctuary to animals subjected to intensive confinement and other "common" agri-business practices and documents the effects of industrialized animal agriculture on animals, the environment and human health. Farm Sanctuary and its supporters are committed to ending cruel practices visited upon animals raised for food. The production of foie gras is unquestionably among the cruelest of industrialized farming practices, and may subject those who consume this product to serious health risks.

Petitioner ALDF is a national non-profit organization involved in every aspect of animal law. ALDF has spent nearly three decades focusing on issues involving animals and the law; its main focus is the use of the legal system to assist courts and legislatures

in carrying out the public policy against animal cruelty and advancing the protection of the interests of animals through the legal system. ALDF's groundbreaking efforts to use the legal system to end the suffering of abused animals are supported by hundreds of dedicated attorneys and more than 120,000 members. ALDF has been involved in the protection of animals used and sold in commercial enterprises, with a focus on cruelty and intensive confinement of animals used for food.

ALDF directs a significant part of its resources towards the protection of animals used for food, both through litigation and through education. ALDF has been instrumental in legal education regarding the law as it applies to all animals, and is the sponsor of over 100 Student Animal Legal Defense Funds (SALDFs). SALDFs are comprised of law students around the country. Each SALDF runs its own programs based on the desire of its members, with multiresource support from ALDF in those programs. ALDF also supports and sponsors various publications on issues pertaining to animal law, and provides support to lawyers involved in important cases seeking to increase the protection of animals in our society.

Some ALDF members eat meat and other products, including poultry products from chickens, turkeys, ducks and geese. These ALDF members seek to ensure the humane treatment of the animals they ultimately consume; they are firmly committed to the protection of those animals while the animals are alive and being raised in American facilities. They are harmed when these animals are treated cruelly or illegally, and have a strong desire to guarantee enforcement of the government's rules and regulations regarding proper treatment of animals prior to slaughter. Additionally, based on substantial medical evidence regarding the health risks of eating force-fed foie gras, those

members who consume these products are fearful that they may contract serious medical illnesses as a result of eating force-fed foie gras or products associated with that product.

Petitioner NYU SALDF at New York University School of Law is a student chapter of the national non-profit charitable organization Animal Legal Defense Fund. NYU SALDF is a recognized student organization of the New York University School of Law, based in the borough of Manhattan, in the state of New York, and is comprised of individuals concerned with issues relevant to the welfare of nonhuman animals, including farmed animals. NYU SALDF promotes a change in the legal status of animals, and works to end the exploitation of animals. NYU SALDF seeks to educate the public regarding the mistreatment of animals and the health implications of animal products, including farmed animals such as the birds used in the production of foie gras. NYU SALDF also engages in legal research, organizes public speaking events, and assists students in developing animal protection careers.

Petitioner Jessica Gorman is a member of petitioner HSUS and a resident of Albany County, New York. Ms. Gorman regularly consumes food products regulated by the United States Department of Agriculture, including meat and poultry products. However, Ms. Gorman avoids eating force-fed foie gras due to the cruelty involved in its processing and diseased nature of the final product. Although Ms. Gorman refuses to eat force-fed foie gras, she would like to eat other duck liver products that are not produced by force feeding, and are therefore not diseased products. However, she cannot eat any duck liver products as she is unable to determine if those products resulted from force-feeding.

Ms. Gorman used to be a representative of a drug company which required her to

attend events with prepared food dishes. She continues, on occasion, to eat at upscale restaurants, catered events, and parties. On these occasions, Ms. Gorman finds it difficult or impossible to identify every ingredient that goes into a final food dish, as there are often no labels describing what a dish contains. Ms. Gorman enjoys trying new foods, and has tried dishes at these events without knowing what they contain. Foie gras could have been used as an ingredient in these dishes and she could have unwittingly eaten it, or could eat it in the future.

Ms Gorman is concerned that the consumption of force-fed foie gras, as currently produced, may increase the risk that she will develop a disease called Secondary Amyloidosis in connection with an inflammatory disease. Secondary Amyloidosis is an extremely serious medical condition, which is difficult to treat and has a high mortality rate. As the disease progresses it affect many bodily organs, leading to an enlarged liver, kidney failure, and ultimately death. Foie gras contains fibrils that may be transmitted to humans, form potential nucleation sites which persist in the host, and support the development of Secondary Amyloidosis when chronic inflammation occurs at a later date. Ms. Gorman does not believe she has an inflammatory disease at this time, but she is concerned because she is only 33 years old and as such could develop one in the future. Force-fed foie gras also poses a second health risk to Ms. Gorman. Ms. Gorman is concerned that the consumption of force-fed foie gras may increase the risk that she will develop Alzheimer's disease. She believes she is already at an increased risk of developing Alzheimer's disease because she has two grandparents who developed it. Ms. Gorman has a strong personal interest in ensuring that all animals raised for human use are treated with compassion, and that the production of poultry products comports with

the PPIA, its implementing regulations, and the Agency's rules mandating the condemnation of fatty, degenerated livers.

Petitioner Doris Booth is an adult individual residing in Thompsonville, New York. Ms. Booth consumes meat and poultry products, but avoids eating force-fed foie gras due to the cruelty involved in the force-feeding process and the nature of the resulting diseased product. As a state licensed wildlife rehabilitator who has cared for many types of wild and domesticated birds, including geese and ducks, Ms. Booth believes the process of force feeding to induce a diseased liver product is incredibly cruel. Ms. Booth is so upset by the force-feeding practice that she avoids driving by Hudson Valley Foie Gras, which is located near her home.

While Ms. Booth avoids eating force-fed foie gras, she does consume food products regulated by the United States Department of Agriculture, including meat and poultry products. Ms Booth is very concerned that she may have unknowingly eaten force-fed foie gras in the past as a food ingredient, or may do so in the future – which has and will continue to put her at an increased food safety risk. Ms. Booth has a strong personal interest in ensuring that all animals raised for human use are treated with compassion, and that the production of poultry products comport with the PPIA, its implementing regulations, and the Agency's rules mandating the condemnation of fatty, degenerated livers.

Petitioner Daniel Stahlie is an adult individual residing in Ossining, New York. Mr. Stahlie regularly consumes food products regulated by the United States Department of Agriculture, including meat and poultry products. Mr. Stahlie also eats force-fed foie gras and other foods containing duck or goose liver, including pâté, when attending

parties and other events. He would prefer to eat duck and goose liver products that do not pose the health and food safety issues discussed in this Petition, but it would be virtually impossible for him, as a consumer, to verify the safety and production method of every piece of food he eats. Mr. Stahlie also used to purchase force-fed foie gras for home consumption but no longer does so due to the production methods involved.

Mr. Stahlie is particularly concerned that the production of force-fed foie gras, as currently produced, may increase his risk of developing a disease called Secondary Amyloidosis in connection with an inflammatory disease. Secondary Amyloidosis is an extremely serious medical condition, which is difficult to treat and has a high mortality rate. Force-fed foie gras contains fibrils that may be transmitted to humans, form potential nucleation sites which persist in the host, and support the development of Secondary Amyloidosis when chronic inflammation occurs at a later date. Mr. Stahlie has a strong personal interest in ensuring that all animals raised for human use are treated with compassion, and that the production of poultry products comport with the PPIA, its implementing regulations, and the Agency's rules mandating the condemnation of fatty, degenerated livers.

III. Action Requested

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution, U.S. CONST. AMEND. 1, the Administrative Procedure Act, 5 U.S.C. § 553(e) (2007), and the USDA's implementing regulation, 7 C.F.R. § 1.28 (2007), the undersigned submit this citizen petition for rulemaking under the PPIA, 21 U.S.C. § 451 *et seq.* (2007), requesting that the Secretary initiate rulemaking to require force-fed foie gras processors to comply with the express intent of

Congress to prevent poultry products which are “unsound, unhealthful, unwholesome, or otherwise unfit for human food,” *id.* at § 453(g)(3), from entering the human food supply -- thereby protecting the public from consuming diseased, adulterated poultry products.

V. Factual Background

A. Production of Force-Fed Foie Gras in the United States

There are only three US facilities known to petitioner that produce and process force-fed foie gras. One is located in California and two are located in New York State. It is estimated that among these three facilities approximately 500,000 birds are slaughtered per year which results in thousands of pounds of force-fed foie gras entering interstate commerce every week.³

One facility, Artisan Foie Gras, is located in Sonoma, California⁴ and the remaining two, Hudson Valley Foie Gras (HVFG) and LaBelle Farms (LaBelle), are both located in New York State.⁵ All three farms produce foie gras using the same cruel force-feeding process, all have their own slaughter and processing facilities and all are subject to the PPIA, its implementing regulations and Agency policy.⁶

³ An HSUS Report: The Welfare of Animals in the Foie Gras Industry (citing personal correspondence with Marcus Henley, operation manager, Hudson Valley Foie Gras, July 6, 2006). *See* Ex. 1.

⁴ While all U.S. foie gras producers discussed in the instant petition use force feeding or “gavage” to create hepatic lipidosis in each bird, the practice and end product will be illegal in California in 2012. On September 30, 2004, California Gov. Schwarzenegger signed SB120 into law. *See* Ex. 2, CAL. HEALTH & SAFETY CODE §§ 25981, 25982 (West 2007). This bill proscribes the production and sale of foie gras in California.

⁵ According to a report produced for HVFG, “New York State is home to two of the U.S.’s three Foie Gras producers.” *See* Ex. 3, Thomas J. Shepstone, Shepstone Management Company, “The Economic Importance of the New York State Foie Gras Industry, Prepared for: Sullivan County Foie Gras Producers,” March 2004.

⁶ All facilities inspected pursuant the Federal Meat Inspection Act or the Poultry Products Inspection Act are assigned an establishment number by the Food Safety and Inspection Service. According to the Meat, Poultry and Egg Product Inspection Directory, Hudson

According to HVFG, an entity based in Ferndale, New York, foie gras is “the fattened liver of a waterfowl . . . produced by a special feeding process.” *See* Ex. 4, Hudson Valley Foie Gras, Inc., “About Hudson Valley Foie Gras: What Is Foie Gras?” HVFG describes its product as liver “characterized by two lobes, putty beige in color, and slightly firm to the touch. Foie gras livers can weigh upwards of two pounds, with the average falling around a pound and a half. About 80 percent of a foie gras is comprised of fat” *See* Ex. 5, Hudson Valley Foie Gras, Inc., “Foie Gras: The Ultimate Millennial Luxury” and “Fresh Foie Gras (Duck), Grade A.” HVFG sells several grades and forms of foie gras, including Grades A, B, and C whole, raw and unprocessed livers. *See* Ex. 6, D’Artagnan Catalog, “Hudson Valley Foie Gras” and Enjoy Foie Gras, “Hudson Valley Fresh Foie Gras Grade B, raw”; Ex. 7, Amazon.com, “Duck Foie Gras,” “Fresh foie gras grade B,” and “Fresh foie gras grade C.”

In addition to HVFG, LaBelle Farm, part of Bella Poultry, Inc., also of Ferndale, New York produces and sells force-fed foie gras. *See* Ex. 8, Prairie Harvest Specialty Foods, “Product & Price List.” Artisan Foie Gras in California also sells comparable force-fed foie gras products. *See* Ex. 9, Artisan Foie Gras, Retail Price List August 2007, (October 25, 2007).

Records produced by the New York Department of Environmental Conservation in response to a request under the Freedom of Information Law, New York Public Officers Law section 84, *et seq.* (McKinney 2007), confirm the production of foie gras in the state and identify the special feeding process noted above as “forced feeding.” *See* Ex. 10, NYDAM,

Valley Foie Gras has two establishment numbers, P17966 and P8757; Artisan Foie Gras, listed as Grimaud Farms of California, has establishment number P18438; and La Belle Farm Inc. has establishment number P19150.

Freedom of Information appeal response, January 25, 2006 (providing an inspection report for Hudson Valley Foie Gras, LLC, foie gras production facility, May 2005); Ex. 11, NYDAM, Freedom of Information request response, November 14, 2005 (providing partial inspection reports for LaBelle Farm, Inc., foie gras production facilities, in 2002-2004).

Interviews of workers employed by HVFG indicate that the feeding process consists of mechanical force-feeding of the subject animals three times a day for a thirty-day period, after which the animal is slaughtered. *See* Ex. 12, Steven Greenhouse, "No Days Off at Foie Gras Farm; Workers Complain, but Owner Cites Stress on Ducks," *The New York Times*, April 2, 2001, at B1. Records produced by the New York Empire State Development Corporation indicate that HVFG currently raises an estimated 250,000 ducks annually for the production of foie gras.

B. Force Feeding Induces Liver Disease in Ducks and Geese

In 1998, the European Union Scientific Committee on Animal Health and Animal Welfare, an official and permanent committee of the European Commission, in response to a request for an official opinion on the production of foie gras, adopted a 93-page official report. In the report, the Committee took up the issue of whether the production method used to produce foie gras induces disease in the subject animals. After noting that "disease is by definition a pathological state where the causal factors are often clearly identified and the clinical signs well defined," the Committee concluded that "because normal liver function is seriously impaired in birds with the hypertrophied liver which occurs at the end of force feeding this level of steatosis *should* be considered pathological." *See* Ex. 13, European Union Scientific Committee on Animal Health and Animal Welfare, "The Report of the European Union Scientific Committee on Animal Health and Animal Welfare on Welfare

Aspects of the Production of Foie Gras in Ducks and Geese,” adopted by the Committee, December 16, 1998, Brussels (emphasis added).

The Committee went on to note that “[i]f birds with good welfare and a large, but not pathologically changed, liver are produced, a high fat content pâté would have to be produced by the addition of fat.” *Id.* In considering mortality rates as an indicator of the pathological effects of the process, the Committee also noted that “[t]he mortality rate in force fed birds varies from 2% to 4% in the two week force feeding period compared with around 0.2% in comparable ducks.” *Id.*

The production of force-fed foie gras, including specific analysis of and reference to the production process at the California and New York facilities described above, has since been examined by national organizations focused on animal health and welfare. Their analyses have uniformly concluded that force-fed foie gras production induces liver disease. *See, e.g.,* Ex. 14, Carol McKenna, “Forced Feeding: An Inquiry Into the Welfare of Ducks and Geese Kept for the Production of Foie Gras,” February 2000. “[A]s a result, various metabolites appear in the blood that are usually stopped by the liver (ammonium, mercaptans, short-chain antigens) and that may then reach the central nervous system (particularly sensitive to these compounds) and trigger central nervous troubles such as circling movements, epileptiform crisis, and increase of the intracranial pressure accompanied by migraines, and finally stupor, coma and death.” *See* Ex. 15, Farm Sanctuary, Inc., “The Welfare of Ducks and Geese in Foie Gras Production: A Summary of the Scientific and Empirical Evidence,” 2004; *see also* Ex. 16, Foundation, French League of Animal Rights, “Critical Analysis of the Report of the Scientific Committee on Welfare Aspects of the Production of Foie Gras in Ducks and Geese,” April 2000, and Ex. 17,

Antoine Comiti, "Rebuttal to the Claim by INRA Researchers that Force-Feeding Is Not Harmful to the Bird's Health and Liver," May 2006.

A recent report published by the New York State Humane Association, an organization comprised of and representing official state humane law enforcement entities throughout the state, refers to the production of foie gras at the New York facilities noted above, and states that "foie gras is made by force feeding ducks . . . for a period of two to four weeks to produce a liver that is so infiltrated with fat as to be grossly distended and is in failure." *See* Ex. 18, New York State Humane Association, "The Foie Gras Industry in New York," Humane Review, Winter 2005 (also referring to the induction of hepatic lipidosis (steatosis) in the liver as a disease, and to resulting diseases including hepatic encephalopathy). As discussed further below, necropsies of birds retrieved from a California foie gras farm also show evidence of hepatic lipidosis. *See infra* Ex. 32.

C. Examination of Animals Used in Foie Gras Production

In 1991, Dr. Ward Stone, New York State Wildlife Pathologist employed by the New York State Department of Environmental Conservation, performed necropsies on two ducks obtained from the foie gras production process at Commonwealth Enterprises, Inc. (a former company that engaged in force-fed foie gras production), also based in Sullivan County, New York, and concluded that the process "creates a diseased condition in each duck," and asked that the process be halted. *See* Ex. 19, Letter of Dr. Ward Stone, New York State Wildlife Pathologist, New York State Department of Environmental Conservation, dated November 14, 1991; *see also* Ex. 20, Letter of Dr. Ward Stone, dated September 2005 (concluding that "the overloading of the liver with lipid (lipidosis) is a pathological process . . ."). Also in 1991, Dr. Wendy Thacher, DVM, provided a report with similar conclusions, based on

necropsies of other ducks taken from the foie gras production process which were performed at the New York State College of Veterinary Medicine. She noted various secondary infections and illnesses attributable to the production process. *See* Ex. 21, Letter of Wendy Thacher, DVM, dated November 15, 1991, and related animal pathology reports from the New York State College of Veterinary Medicine, dated December 6, 1991.

One year later, after a police investigation of Commonwealth Enterprises, three veterinarians, including Dr. Thacher, reiterated these conclusions, based on their personal visits to the production facility and their viewing of hundreds of animals used in the production process — many or most of whom exhibited symptoms consistent with the diseases and illnesses described above. *See* Ex. 22, Letter of Lucille R. Kaplan, dated April 3, 1992, with affidavits by Dr. Tatty Hodge, Dr. Mark Lerman, and Dr. Wendy Thacher attached thereto.

In 2002 and 2003, necropsies performed on birds used by HVFG in its foie gras production process confirmed that the animals suffered from severe hepatic lipidosis and other related illnesses such as pneumonia. *See* Ex. 23, Affidavit of Sarahjane Blum, dated May 26, 2006, and attachments thereto. Video and photos taken at the facility showed animals exhibiting the symptoms of illnesses consistent with literature analyzing foie gras production and its impact on animal health. *See* Ex. 24, Affidavit of Ryan Noah Shapiro, dated May 20, 2006, and attachments thereto.

Again in 2005, necropsies on several ducks used in HVFG's foie gras production process performed at Cornell University by New York State Wildlife Pathologist Dr. Ward Stone, showed ducks suffering from hepatic lipidosis, pneumonia, secondary infections, and other maladies attributable to the production process. *See* Ex. 25,

Affidavit of Holly Cheever, DVM, dated May 8, 2006, and attachments thereto.⁵ It was determined that hepatic lipidosis and related illnesses caused the death of the animals. An analysis of feed actually used in the production process confirmed that, consistent with the literature described above, such feed was nutritionally inadequate and a contributing factor to the disease. *See id.*; Ex. 26, Affidavit of Greg J. Harrison, DVM, DABVP, DECAMS, dated May 25, 2006, and attachments thereto. Furthermore, video and photos taken at the facility showed dozens of birds exhibiting the expected symptoms and the corpses of birds that likely died as a result. *See* Ex. 27, Affidavit of John Doe, dated May 22, 2006, and attachments thereto; Ex. 28, Affidavit of Meghan Beeby, dated May 11, 2006, and attachments thereto; Ex. 25, Affidavit of Dr. Holly Cheever, DVM, dated May 8, 2006, and attachments thereto.⁶

⁵ *See also* Ex. 49, Letter of Dr. Holly Cheever, DVM, dated February 7, 2005 (describing in detail the symptoms these animals exhibit when afflicted with hepatic lipidosis and related illnesses); Ex. 50, Letter of Dr. Holly Cheever, DVM, dated January 29, 1997 (describing in detail her visit to HVFG, including the conditions and state of the animals she encountered therein).

⁶ These veterinarians' findings are also consistent with a recent statement regarding foie gras production adopted by over 1,600 licensed veterinarians. Among other findings, the veterinarians stated that

Necropsies performed on birds from foie gras producers show lesions, including but not limited to: hepatic lipidosis; esophageal trauma secondary to insertion of the feeding pipes (granulomas, fungal and bacterial infections, ruptured esophagi); also fractured limbs, crop impaction, aspiration pneumonia, and ruptured livers. In many cases since the food is observed to be spilling out of their esophagi, mouths, and nares, pathologists have determined that the birds died during the force feeding process.

See Ex. 29, Affidavit of Teresa Barnato, dated May 24, 2006, and attachments thereto. *See also* Ex. 30, Petition of New York state licensed veterinarians supporting anti-foie gras legislation.

Necropsies performed on birds taken from force-fed foie gras production facilities in California also show that the animals suffered from hepatic lipidosis and a variety of other illnesses caused by the production process, all completely consistent with the analysis of the animals described above, and consistent with literature on the production process. *See* Ex. 31, Michelle Locke, "Activists Decry How Ducks Are Raised for Foie Gras; French Delicacy Made From Livers of Force-Fed Ducks," The San Diego Union Tribune, December 3, 2003, at A11; Ex. 32, Affidavit of Dr. Bruce Max Feldmann, DVM, dated April 8, 2006, and attachments thereto; Ex. 33, Affidavit of Bryan Pease, Esq., dated May, 8, 2006; Ex. 34, Affidavit of Dr. Laurie Siperstein-Cook, DVM, dated May 25, 2006, and attachments thereto.

D. Experts' Opinions Regarding Foie Gras and Specific Animals Used in Foie Gras Production

Yvan Beck, DVM, one of the foremost specialists in the world on foie gras production, and upon whom the European Union Scientific Committee on Animal Health and Animal Welfare relied in part in its 1998 report, states that

[t]he direct consequence of a chronic accumulation of lipids in the hepatic cell (steatosis) is the progressive appearance of secondary necrotic phenomena which, at the end of their evolution, will cause a generalized fibrosis of this organ. All the liver diseases causing a fibrosis interfere with the hepatic vascularization and are at the origin of vascular anastomoses. These shunts bypass the hepatocyte, an intermediary between the splanchnic circulation and the portal system. They also cause the manifestations of hepatic encephalopathy described.

See Ex. 35, Affidavit of Dr. Yvan Beck, dated May 10, 2006, and attachments thereto; Ex. 36, Dr. Yvan Beck, "Force-feeding of Palmipeds and Foie Gras Production: The Global Review of a Choice Made By Society," for the Licence Interfacultaire en Environment, Free University of Brussels, 1994; Ex. 37, Beck Y, Guilmot JM, Heymann

M, Van Bercham V, "Report on force feeding by Belgian Experts," presented to the Permanent Council of the European Convention on the Protection of Farmed Animals, Strasbourg, 1996. Dr. Beck also notes that the evidence described above regarding foie gras production in New York is consistent with his general findings.

Greg Harrison, DVM, DABVP, DECAMS, a leading author and recognized expert in avian medicine, having analyzed the various necropsies and other evidence regarding foie gras production in New York, and relying on treatises and recently published studies, states that the evidence indicates

various forms of what is generally known as hepatic lipidosis, a disease indicated by yellow discoloration and hepatomegaly (enlargement) of the liver due to fatty degeneration and subsequent impairment of the parenchymal cells, which can eventually lead to liver failure and death of birds diagnosed with it. Put simply, the cellular changes associated with hepatic lipidosis alter the ability of the liver to function normally, resulting in impaired animal health and if left untreated, death.

See Ex. 26, Affidavit of Greg J. Harrison, DVM, DABVP, DECAMS, dated May 25, 2006, and attachments thereto.

Robert E. Schmidt, DVM, PhD, DACVP, a board-certified veterinary pathologist, avian medicine expert, and author of several authoritative texts on avian pathology, concludes that "[h]epatic lipidosis can be accompanied by various clinical signs including anorexia, depression, diarrhea, biliverdinuria, obesity, poor feathering, dyspnea, and abdominal enlargement, and via impairment of the liver's function, may lead to hepatic encephalopathy, with clinical signs of seizures, ataxia, and muscle tremors." See Ex. 38, Affidavit of Robert E. Schmidt, DVM, PhD, DACVP, dated May 11, 2006, and attachments thereto.

In addition to relying on various published studies, and an examination of the various

necropsies and other evidence regarding foie gras production in New York described above, Dr. Schmidt personally examined samples of livers from birds used in force-fed foie gras production at HVFG and LaBelle, and determined that:

all of the liver samples showed abnormal hepatocytes (liver cells), representing a pathological condition, which would impair cellular functions, and which in turn can lead to clinical illness. This condition, known as hepatic lipidosis or hepatic steatosis, is well documented in published literature, and recognized as a metabolic disease.

Id. His general conclusion regarding the disease and its relation to the foie gras production process is consistent with the opinion of other leading avian veterinarians and avian pathologists in the field, including Dr. H.L. Shivaprasad. *See* Ex. 39, H.L. Shivaprasad, "An Overview of Avian Pathology," California Veterinary Diagnostic Laboratory System, Fresno Branch, University of California, Davis (referring to hepatic lipidosis as a disease); Ex. 40, Holly Nash, DVM, MS, "Fatty Liver (Hepatic Lipidosis)," Veterinary Services Department, Drs. Foster & Smith, Inc.

Dr. Schmidt's conclusion is also consistent with those of other leading animal welfare experts, including Dr. Ian Duncan, Chair of Animal Welfare at the University of Guelph; Dr. Christine Nicol, Professor of Animal Welfare at the University of Bristol; and Dr. Nedim C. Buyukmihci, Professor of Veterinary Medicine (Emeritus) at the University of California, Davis. *See* Ex. 41, Letter of Dr. Ian Duncan, dated February 4, 2004; Ex. 42, Letter of Dr. Christine Nicol, dated February 3, 2004; Ex. 43, Letter of Dr. Nedim C. Buyukmihci, V.M.D., dated February 12, 2004.

E. Experts' Opinions Regarding Potential Human Health Risks from Foie Gras Consumption

Apart from the cruelty and the overwhelming evidence that the force-feeding process results in a diseased liver, the end product itself may cause health risks to a

significant portion of its consumers. Dr. Alan Solomon, M.D., a researcher at the University of Tennessee Graduate School of Medicine and director of the Human Immunology and Cancer/Alzheimer's Disease and Amyloid-Related Disorders Research Program, led a team of scientists that published a study finding that amyloid was present in foie gras purchased from commercial vendors. They concluded that an amyloid-containing food product, specifically foie gras, "hastened the development of amyloid protein A amyloidosis in a susceptible population [of humans]." See Ex. 44, Alan Solomon *et al.*, *Amyloidogenic Potential of Foie Gras*, 104 PROC. NAT'L ACAD. SCI. 10998 (2007).

Based on their experiment, using commercial foie gras, the authors determined that

exposure to exogenous substances with [amyloid enhancing factor] activity also may be an important epigenetic or environmental factor in the development of AA amyloidosis in a susceptible population. In this regard, it would seem prudent for children and adults with rheumatoid arthritis or other diseases who are at risk for this disorder to avoid foods that may be contaminated with AA fibrils. . . . Further, the fact that chemically heterologous fibrils can serve as [amyloid enhancing factor] . . . suggests that it may be hazardous for individuals who are prone to develop other types of amyloid-associated disorders, e.g. Alzheimer's disease or type II diabetes, to consume such products.

Id.

Dr. Alexander Steven Whitehead, D.Phil., a Professor of Pharmacology at the University of Pennsylvania School of Medicine, has researched Serum Amyloid A, Amyloid A, and Serum Amyloid P (materials associated with Secondary Amyloidosis) since 1984. It is his opinion that amyloid protein A ("AA") amyloidosis, also known as Secondary Amyloidosis, is an extremely serious medical condition in humans, which is difficult to treat and has a high mortality rate. See Ex. 45, Affidavit of Dr. Whitehead, ¶

It is Dr. Whitehead's opinion that

AA Amyloid fibrils are present in duck foie gras, and that the similarity between SAA in mammals and birds makes it likely that AA from duck foie gras would be able to survive in the human stomach, be absorbed through the human intestinal tract and ultimately form potential nucleation sites in major human organs. Therefore, avoidance of foods that may be contaminated with AA fibrils, such as duck foie gras, might be important for those who have an inflammatory disease, like rheumatoid arthritis, or who could develop an inflammatory disease in the future. Such individuals may be placed at an increased risk of developing Secondary (or AA) Amyloidosis from eating foie gras containing AA fibrils.

Id. at ¶ 5. Dr. Whitehead also explains that the Solomon *et al.* article raises the possibility that AA fibrils, such as those in foie gras, may lead to the development of other amyloid diseases, including Alzheimer's disease. *Id.* at ¶ 29.

This information is particularly alarming when considering the number of people who face an increased risk of harm through the consumption of force-fed foie gras. Consumers with inflammatory diseases face an increased risk of developing secondary amyloidosis. Additionally, there a multitude of known inflammatory diseases affecting millions of Americans. This is illustrated by looking at the numbers of those affected by only one relatively common inflammatory disease: rheumatoid arthritis. The Medical College of Wisconsin reports that approximately 2.1 million people, or 1% of the population have rheumatoid arthritis.⁷

Those Americans with inflammatory diseases are not the only members of the population who are at risk. Consumption of force-fed foie gras may lead to an increased risk in the development of other amyloid diseases such as Alzheimers and type II

⁷ See Ex. 46, Medical College of Wisconsin, *RheumatoidArthritis* (October 25, 2007), available at <http://healthlink.mcw.edu/article/952625523.html>.

diabetes. The AGS Foundation for Health In Aging reports that Alzheimer's accounts for more than half of all adult dementia ("AD"), affecting approximately 4 million Americans. Because the incidence of AD increases with age -- it afflicts 10% of 65-year-olds compared to 50% of those 85 and older -- the Alzheimer's population is expected to double as the Baby Boom generation matures over the next 20 years.⁸ Furthermore, Scott R. Votey, MD, Assistant Dean for Graduate Medical Education and Professor of Medicine/Emergency Medicine at the David Geffen School of Medicine at UCLA writes that approximately 13 million people in the United States have a diagnosis of diabetes, and diabetes is undiagnosed in another 5 million. Approximately 10% have type 1 diabetes, and the rest have type 2.⁹ This means that approximately 16.2 million Americans have type II diabetes.

If one only considers the number of those with Alzheimer's disease, rheumatoid arthritis and type II diabetes, approximately 22.3 million Americans are implicated. That number represents only a portion of the population at risk from the consumption of force-fed foie gras, but is staggering nonetheless.

VI. Legal Grounds for the Petitioned Action

The PPIA was enacted in order to "prevent the movement or sale in interstate or foreign commerce of . . . poultry products which are adulterated or misbranded." 21 U.S.C. § 452 (2007). The term "adulterated" applies to any poultry product if "it consists in whole or in part of any filthy, putrid, or decomposed substance *or* is for any other

⁸ See Ex. 47, The AGS Foundation for Health In Aging, *What is Alzheimer's: An Introduction to Diagnosis and Treatment* (October 25, 2007), available at http://www.healthinaging.org/public_education/alz_what_is.php.

⁹ See Ex. 48, Scott R. Votey, MD, *Diabetes Mellitus, Type 2 – A Review*, (October 25, 2007), available at <http://www.emedicine.com/emerg/topic134.htm>.

reason *unsound, unhealthful, unwholesome, or otherwise unfit for human food.*” *Id.* at § 453(g)(3) (emphasis added). *See also* 9 C.F.R. § 381(d)(iii) (2007). Once poultry products are found to be adulterated, those products shall be condemned. 21 U.S.C. § 455(c) (2007). A “poultry product” is defined as “any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof . . .” 21 U.S.C. § 453(f) (2007). Force-fed foie gras fits squarely within this definition as a diseased product, and thus rulemaking should be initiated to exclude processors from releasing it into the human food supply.

VII. Conclusion

The foregoing evidence, and all of the appended exhibits and attachments thereto, demonstrate that force-fed foie gras is the product of a diseased animal, that the livers comprising such foie gras are fatty and degenerated, and that a significant portion of consumers face an increased health risk from its consumption. Accordingly, petitioners respectfully request that the Secretary initiate rulemaking to exclude force-fed foie gras from the human food supply as it is “unsound, unhealthful, unwholesome, or otherwise unfit for human food.”

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of petitioner's Petition for Rulemaking and all materials in support thereof, was served this 28th day of November, 2007 by hand delivery to:

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