



December 1, 2016

Alfred V. Almanza
Deputy Under Secretary for Food Safety
and Acting FSIS Administrator
Food Safety and Inspection Service
1400 Independence Ave., S.W.
Washington, DC 20250-3700

Dear Mr. Almanza:

The enclosed petition requests that the Food Safety and Inspection Service take action to inform the public about the recognized and avoidable risk of developing colorectal cancer from frequent consumption of processed meat and poultry. It is based on the convincing scientific evidence presented by the International Agency for Research on Cancer, the World Cancer Research Fund International, and the American Cancer Society that the risk of colorectal cancer increases by roughly 18 percent for every 50 grams of processed meat and poultry consumed daily.

The evidence, statutory authority and legal precedent for requiring a warning label on processed meat is outlined in the petition.

The Center for Science in the Public Interest (CSPI) is a nonprofit, non-governmental, consumer-advocacy organization focused primarily on nutrition, health, and food safety issues. CSPI is supported by subscribers to its *Nutrition Action HealthLetter* and by foundation grants, and does not accept government or industry funding.

Sincerely,

Michael F. Jacobson, Ph.D.
President
Center for Science in the Public Interest

Enclosure

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

)	
Petition for a Label on Processed Meat)	
and Poultry Products Warning the Public)	Docket No. _____
that Frequent Consumption May Increase)	
the Risk of Colorectal Cancer)	
)	

CITIZEN PETITION

Submitted by:

Center for Science in the Public Interest

December 1, 2016

FSIS Docket Clerk
Department of Agriculture
Food Safety and Inspection Service
Room 2534 South Building
1400 Independence Avenue, S.W.
Washington, DC 20250-3700

INTRODUCTION

Americans eat considerable amounts of fresh and processed meat and poultry. In 2013, the average American consumed 71 pounds of red meat and 55 pounds of poultry,¹ with processed meat constituting at least 22 percent of total meat and poultry consumption.² In recent years, scientific research has led to the conclusion that processed meat and poultry increases the risk of colorectal cancer,³ which is the second-leading cause of cancer deaths in the United States, and expected to account for 49,190 deaths in 2016.⁴ The Food Safety and Inspection Service ("FSIS") is responsible for safeguarding the public by ensuring that the labels on meat and poultry products provide consumers with information about nutrition, ingredients, and health risks. In this petition we request that FSIS require a label on processed meat and poultry products informing the public that their frequent consumption may increase the risk of colorectal cancer.

CITIZEN'S PETITION

ACTION REQUESTED

Pursuant to 5 U.S.C. § 553(e), 9 C.F.R. § 392, and 7 C.F.R. § 1.28, petitioners request that the Food Safety and Inspection Service issue a regulation amending 9 C.F.R. §§ 317 and 381 to require a label on packages of processed meat and poultry as follows:

§ 317.2 Labels; definition; required features.

* * * * *

(_)(1) All meat products that are preserved by smoking, curing, salting, and/or the addition of chemical preservatives shall bear the labeling statement:

USDA WARNING: Frequent consumption of processed meat products may increase your risk of developing cancer of

¹ USDA Econ. Research Serv., Red Meat: Per Capita Consumption Adjusted for Loss.

² Carrie R. Daniel, et al., *Trends in Meat Consumption in the United States*, 14 Public Health Nutrition 575 (2011). (The 22 percent estimate is low because the study left out certain cured meats, such as bacon and ham, from its definition of processed meat.)

³ The studies are discussed in the Factual Basis section of this petition.

⁴ Am. Cancer Society, Key Statistics for Colorectal Cancer, (2016) at <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics> (Last Accessed Nov. 4, 2016).

the colon and rectum. To protect your health, limit your consumption of such products.

(2) The warning statement shall be prominently placed with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) The words “USDA WARNING” shall be capitalized and shall appear in bold type.

(4) The warning statement shall be set off in a box by the use of hairlines.

§ 381.125 Special handling label requirements.

* * * * *

(_)(1) All poultry products that are preserved by smoking, curing, salting, and/or the addition of chemical preservatives shall bear the labeling statement:

USDA WARNING: Frequent consumption of processed poultry products may increase your risk of developing cancer of the colon and rectum. To protect your health, limit your consumption of such products.

(2) The warning statement shall be prominently placed with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) The words “USDA WARNING” shall be capitalized and shall appear in bold type.

(4) The warning statement shall be set off in a box by the use of hairlines.

ABOUT THE PETITIONER

The Center for Science in the Public Interest (“CSPI”), founded in 1971 and located in Washington, D.C., is a nonprofit, non-governmental, consumer-advocacy organization focused primarily on nutrition, health, and food safety issues.

FACTUAL BASIS

Processed meat is produced by smoking, curing, salting, and/or the addition of chemical substances such as nitrate and nitrite to preserve the meat and enhance its flavor.⁵ Nitrite used in the curing process performs an additional function of inhibiting the

⁵ This definition is consistent with others for the term processed meat. *Compare* “Processed meat refers to meat that has been transformed through salting, curing, fermentation, smoking, or other processes to enhance flavour or improve preservation. Most processed meats contain pork or beef, but might also contain other red meats, poultry, offal (e.g., liver), or meat byproducts such as blood.” Véronique Bouvard, et al., *Carcinogenicity of Consumption of Red and Processed Meat*, 16 *The Lancet Oncology* 1599 (2015); “Processed meat [and] processed poultry [are] products preserved by smoking, curing, salting, and/or the addition of

growth of *Clostridium botulinum* spores. Processed meat has been included in the human diet since antiquity and its preparation was the principal method for preserving meat before the 20th century. Examples of processed meats include bacon, hot dogs, ham, sausages, and deli or luncheon meats. For purposes of this petition, the term “processed meat” refers to any processed meat or poultry product.

CSPI is submitting this petition because convincing scientific evidence demonstrates that frequent consumption of processed meat carries a recognized and avoidable risk to public health to which consumers should be alerted. The most recent review of the evidence was conducted by the International Agency for Research on Cancer (“IARC”) which announced on October 26, 2015, that processed meat is “carcinogenic to humans.”⁶ The IARC is an agency of the World Health Organization that is charged with coordinating and conducting research on the causes of human cancer. Its monograph is the latest in a series of reports concluding that consumption of processed meat increases the risk of colorectal cancer. The World Cancer Research Fund International (“WCRF”) in association with its affiliate the American Institute for Cancer Research (“AICR”) and the Imperial College London reported in 2011 that processed meat is a convincing cause of colorectal cancer.⁷ The American Cancer Society (“ACS”) advises the public to “minimize consumption of processed meats such as bacon, sausage, luncheon meats, and hot dogs” based on evidence that the risk of colorectal cancer increases by 15 to 20 percent for every 50 grams consumed daily.⁸ Researchers estimate that in 2015, roughly 5,000 deaths from colorectal cancers in the United States were attributable to diets high in processed meat.⁹ In spite of firm conclusions reached by WCRF, AICR and others, public awareness of the cancer risk due to processed meats is low. A 2015 poll by the AICR found that only about one in three Americans knew that consumption of processed meat is a significant factor in developing cancer.¹⁰

The evidence that processed meat causes cancer in humans comes largely from epidemiological studies. That evidence is supported by mechanistic evidence from studies

chemical preservatives. Processed meats and poultry include all types of meat or poultry sausages (bologna, frankfurters, luncheon meats and loaves, sandwich spreads, viennas, chorizo, kielbasa, pepperoni, salami, and summer sausages), bacon, smoked or cured ham or pork shoulder, corned beef, pastrami, pig’s feet, beef jerky, marinated chicken breasts, and smoked turkey products.” U.S. Dept. of Health and Human Serv. and USDA, 2015-2020 Dietary Guidelines for Americans, (8th Ed., 2015); and “[The] common thread is [that] processed meats are fresh products that have been changed from their original state.” and “Processed meats are commonly made from beef, pork, chicken and turkey...” Am. Meat Inst., *Processed Meats: Convenience, Nutrition, Taste: American Traditions and Iconic Foods* (undated).

⁶ Press Release, Internat’l Agency for Research on Cancer, IARC Monographs Evaluate Consumption of Red Meat and Processed Meat (Oct. 26, 2015) available at https://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr240_E.pdf (Last Accessed Oct. 14, 2016).

⁷ World Cancer Research Fund/Am. Inst. for Cancer Research, Continuous Update Project Report: Food, Nutrition, Physical Activity, and the Prevention of Colorectal Cancer (2011).

⁸ Lawrence H. Kushi, et al., *American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention*, 62 CA Cancer J. Clin. 30, 40, 2012.

⁹ Global Burden of Disease Inst. for Health Metrics and Evaluation, GBD Compare | Viz Hub display of deaths from colon and rectum cancer attributable to diets high in processed meat for both sexes and all ages in 2015, available at <http://vizhub.healthdata.org/gbd-compare/> (Last Accessed Nov. 4, 2016).

¹⁰ Am. Inst. for Cancer Research, The AICR 2015 Cancer Risk Awareness Survey Report.

on humans and animals.¹¹ (Randomized clinical trials testing the impact of processed meats on colorectal cancer risk would not be feasible or ethical.)

An IARC working group of 22 scientists from 10 countries concluded that the consumption of processed meat is “carcinogenic to humans (Group 1) on the basis of sufficient evidence for colorectal cancer.”¹² According to IARC, a majority of the highest-quality cohort studies, including studies from the United States, reported that the consumption of processed meat is associated with an increased risk of colorectal cancer.¹³ Furthermore, a meta-analysis of nine cohort studies reported a statistically significant 18 percent increased risk of colorectal cancer for every 50 grams of processed meat consumed daily.¹⁴ To put the increased risk into perspective, a typical serving of ham, sausage, bologna, or hot dog weighs 55 grams.¹⁵ The IARC concluded that the “large amount of data and the consistent associations of colorectal cancer with consumption of processed meat across studies in different populations [make] chance, bias, and confounding unlikely as explanations” for the consistent association between processed meat and colorectal cancer, leading the working group to conclude that “there is sufficient evidence in human beings for the carcinogenicity of the consumption of processed meat.”¹⁶

Similarly, the 2011 WCRF report concluded that “processed meat is a convincing cause of colorectal cancer.”¹⁷ The report’s meta-analysis of 13 studies found an 18 percent increased risk for colorectal cancer for every 50 grams of processed meat consumed per day.¹⁸ The results are similar to those from a 2009 meta-analysis which found a 19 percent increased risk for that cancer in people who consumed the highest versus the lowest amount of processed meat.¹⁹ According to the WCRF report, a substantial amount of evidence, with a dose-response relationship apparent from cohort studies, and strong

¹¹ Bouvard, *supra* note 5.

¹² *Id.* The current estimated publication date for the full IARC monograph is the summer of 2017. Email from Helene Lorenzen, Assistant for IARC Monographs Section, to Michael Farr, CSPI Food Law and Regulatory Policy intern (June 1, 2016)(on file with CSPI).

¹³ Teresa Norat, et al., *Meat, Fish, and Colorectal Cancer Risk: the European Prospective Investigation into Cancer and Nutrition*, 97 J. Nat’l Cancer Inst. 906 (2005); Shino Oba, et al., *The Relationship Between the Consumption of Meat, Fat, and Coffee and the Risk of Colon Cancer: a Prospective Study in Japan*, 244 Cancer Letter 260 (2006); Adam M. Bernstein, et al., *Processed and Unprocessed Red Meat and Risk of Colorectal Cancer: Analysis by Tumor Location and Modification by Time*, 10 PLoS One e0135959 (2015); Amanda J. Cross, et al., *A Large Prospective Study of Meat Consumption and Colorectal Cancer Risk: An Investigation of Potential Mechanisms Underlying this Association*, 70 Cancer Research 2406 (2010); Ann Chao, et al., *Meat Consumption and Risk of Colorectal Cancer*, 293 JAMA 172 (2005).

¹⁴ Doris S.M. Chan, et al., *Red and Processed Meat and Colorectal Cancer Incidence: Meta-Analysis of Prospective Studies*, 6 PLoS One e20456 (2011).

¹⁵ Table 2—Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply, 9 C.F.R. § 317.312 (2016)

¹⁶ Bouvard, *supra* note 5.

¹⁷ World Cancer Research Fund, *supra* note 7.

¹⁸ *Id.*

¹⁹ Rachel R. Huxley, et al., *The Impact of Dietary and Lifestyle Risk Factors on Risk of Colorectal Cancer: A Quantitative Overview of the Epidemiological Evidence*, 125 Internat’l J. Cancer 171 (2009).

evidence for plausible mechanisms operating in humans is consistent with the conclusion that processed meat is a convincing cause of colorectal cancer.²⁰

The exact mechanism by which processed meat increases the risk of colorectal cancer is unknown. However, multiple meat components provide “substantial supporting mechanistic evidence,” according to the IARC.²¹ For example, “meat processing, such as curing and smoking, can result in formation of carcinogenic chemicals, including N-nitroso-compounds (NOC) and polycyclic aromatic hydrocarbons (PAH). Furthermore, studies have demonstrated that the consumption of processed meat leads to the formation of NOC in the gastrointestinal tract.”²²

The meat industry has challenged efforts to regulate substances added to processed meat based on the mechanistic evidence. That has happened most recently with the California Environmental Protection Agency proposal to list nitrite in combination with amines or amides as a carcinogen under the state’s Safe Drinking Water and Toxic Enforcement Act (Proposition 65).²³ The meat industry cites studies finding uncertainty about the role of nitrite in its opposition to the proposal.²⁴ Such studies are not relevant to this petition, however, because its arguments are based not on the mechanism, but on the strength of the epidemiological evidence, which is sufficient to establish risk and obligate USDA to require the industry to inform consumers about the risk of consuming processed meats.

FSIS already employs this approach with regard to other risks that may be difficult to control at the processing level and, therefore, must be managed by the consumer. For instance, processed meat that was cured without using nitrate or nitrite must be labeled as “Uncured” and include the statements “No Nitrate or Nitrite Added” and “Not Preserved – Keep Refrigerated Below 40° F. At All Times” on its packaging to inform consumers how to manage the risk from *Clostridium botulinum*.²⁵ FSIS requires safe-handling instructions on raw meat and poultry products to warn the public about the risk of bacterial pathogens on

²⁰ World Cancer Research Fund, *supra* note 7.

²¹ Bouvard, *supra* note 5.

²² J.C. Lunn, et al. *The Effect of Haem in Red and Processed Meat on the Endogenous Formation of N-nitroso Compounds in the Upper Gastrointestinal Tract*, 28 *Carcinogenesis* 685 (2007); Annemiek M.C.P. Joosen, et al., *Effect of Processed and Red Meat on Endogenous Nitrosation and DNA Damage*, 30 *Carcinogenesis* 1402 (2009).

²³ Calif. Environmental Protection Agency, Notice of Intent to List: Nitrite in Combination with Amines or Amides, (2014) available at <http://oehha.ca.gov/proposition-65/crn/notice-intent-list-nitrite-combination-amines-or-amides> (Last Accessed Nov. 7, 2016).

²⁴ Letter to Cynthia Oshita, OEHHA, from Betsy Booren, vice president, scientific affairs, American Meat Inst. (May 8, 2014) available at <http://oehha.ca.gov/media/downloads/proposition-65/crn/comments/0515144aminonitrite.pdf> (Last Accessed Nov. 7, 2016); and Letter to Cynthia Oshita, OEHHA, from Barry Carpenter, CEO of the North Am. Meat Ass’n (May 8, 2014) available at <http://oehha.ca.gov/media/downloads/proposition-65/crn/comments/0515147naminonitrite.pdf> (Last Accessed Nov. 7, 2016).

²⁵ See, Nitrates and Nitrites: Proposed Rule, 43 Fed. Reg. 18193 (Apr. 28, 1978) (Final rule codified at 9 C.F.R. §§ 316.10(d) & 317.17 (2016)).

mishandled or improperly cooked product.²⁶ Mechanically tenderized beef must be labeled to inform consumers that the meat presents a greater risk that pathogenic bacteria may survive normal cooking than would be the true for intact cuts of meat.²⁷

The mechanically tenderized meat label is particularly relevant to this petition. FSIS reasoned in its rulemaking that mechanically tenderized meat is indistinguishable from intact cuts, and therefore misbranded if not labeled.²⁸ FSIS has on other occasions required processors to label food with material facts that would not be evident to consumers in the absence of labeling.²⁹ For example, the source of natural sausage casings must be labeled if they are derived from a different type of meat or poultry than is encased in the sausage. The purpose of the requirement is to keep consumers from being misled into eating food that, whether for health, religious, or other reasons, they would not want to consume.³⁰ The same reasoning applies to the request made by this petition, which asks FSIS to address a matter of serious public health concern (indeed, greater than the several examples just given) by following its well-established practice of requiring meat and poultry to be labeled with information material to protecting public health.

LEGAL BASIS

The Federal Meat Inspection Act (“FMIA”), 21 U.S.C. § 601, et seq., and Poultry Products Protection Act (“PPIA”), 21 U.S.C. § 451, et seq., provide FSIS with authority to undertake the action requested in this petition. Under §§ 602 and 451, FSIS is charged with regulating the meat and poultry industry to protect the health and welfare of consumers by assuring that meat and poultry is wholesome, not adulterated, and properly marked, labeled, and packaged. Food is misbranded under §§ 601(n)(1) and 453(h)(1) “if its labeling is false or misleading in any particular.” FSIS has the authority to make “rules and regulations as are necessary for the efficient execution of the provisions” of the FMIA and PPIA under §§ 621 and 463(b). This has been described as broad authority to enact regulations and require other information to carry out its responsibility.³¹

The authority listed above directs the agency to give favorable consideration to the request made by this petition. Under the agency’s interpretation of §§ 601(n) and 453(h) processed meat is misbranded if its label fails to reveal material facts “with respect to consequences which may result from the use of the food... under conditions of use as are customary or usual.”³² Materiality looks at “inherent characteristics of the food itself,”³³

²⁶ Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 59 Fed. Reg. 14528 (March 28, 1994).

²⁷ Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products, 80 Fed. Reg. 28153, 28155 (May 18, 2015).

²⁸ *Id.*

²⁹ *See*, Irradiation of Meat Food Products, 64 Fed. Reg. 72150, 72157 (Dec. 23, 1999).

³⁰ Labeling of Natural or Regenerated Collagen Sausage Casings, 66 Fed. Reg. 40843 (Aug. 6, 2001).

³¹ *Nat’l Pork Producers v. Bergland*, 931 F.2d 1353, 1362 (8th Cir., 1990).

³² Letter to Pamela Geller, executive director of SIOA, from Daniel Engeljohn, assistant administrator of the Office of Policy and Program Development, FSIS (Sept. 9, 2016).

³³ *Id.*

and whether that characteristic would affect consumer actions. FSIS applied this interpretation to find that the source of sausage casing is material because consumers could be misled into eating a food they consider unhealthy if that information is missing.³⁴ Under that reasoning, processed meat should be labeled because of the risk of colorectal cancer resulting from its frequent consumption. Such information about an inherent characteristic of the food would be a factor in a consumer's decision to eat unhealthy amounts of processed meat and is, therefore, material.³⁵

Labeling requirements that might discourage people from buying a product have been questioned in the past as violating First Amendment protections.³⁶ Concern that the label may constitute prohibited compelled speech under the Constitution does not pose a barrier to FSIS granting this petition. The label requested serves a substantial governmental interest in protecting public health, directly advances that interest, and is no more intrusive than necessary to achieve that interest.³⁷ It provides consumers with information that is factual and uncontroversial in that the link between consumption of processed meat and colorectal cancer is well supported by the evidence.³⁸

CONCLUSION

In light of the strong scientific evidence that the frequent consumption of processed meat increases the risk of colorectal cancer, the agency must act decisively to require a label on processed meat stating that frequent consumption may increase the risk of colon and rectal cancer. We urge the agency to grant this petition.

³⁴ Labeling of Natural or Regenerated Collagen Sausage Casings, *supra* note 30.

³⁵ Market research in the United Kingdom found a 15.7 percent drop in sales of pre-packaged sausage and a 17 percent drop in sales of pre-packaged bacon in the two weeks following the IARC announcement, demonstrating that consumers value and use information about cancer risks in making purchasing decisions. Jeremy Gerrard, *UK Processed Meat Sales Slide after WHO Cancer Report*, Food Engineering Mag. (Dec. 2, 2015), available at <http://www.foodengineeringmag.com/articles/94903-uk-processed-meat-sales-slide-after-who-cancer-report> (Last Accessed Nov. 18, 2016).

³⁶ See, *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014); *Irradiation of Meat and Food Products*, 64 Fed. Reg. at 72158.

³⁷ *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 563 (1980).

³⁸ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Am. Meat Inst.*, 760 F.3d 18.

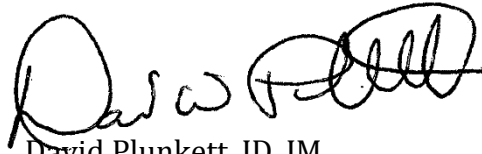
CERTIFICATION

The undersigned certify that to the best of their knowledge and belief this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael F. Jacobson". The script is fluid and cursive.

Michael F. Jacobson, Ph.D.
President
Center for Science in the Public Interest

A handwritten signature in black ink, appearing to read "David Plunkett". The script is fluid and cursive, with a large initial "D".

David Plunkett, JD, JM
Senior Staff Attorney
Center for Science in the Public Interest