EnviroWatch, inc.
www.EnviroWatch.org
PO Box 89-3062, Mililani, HI 96789
envirowatch@envirowatch.org
ph/fx: 808-625-2175

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March 6, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20582

Re: Citizen Petition Requesting FDA to Enforce Ban on Carbon Monoxide Gas in Fresh Tuna Packaging

Dear Sir/Madam:

The attached Citizen Petition is submitted by EnviroWatch, Inc a non-profit 501(C)(3) organization committed to putting an end to environmental injustice by way of investigating and exposing environmental degradation, habitat destruction, poaching, clear cutting, pollution, animal cruelty, and government waste and abuse. This Citizen Petition requests that the FDA take immediate action to enforce a ban on carbon monoxide in the packaging of fresh tuna and fresh tuna that is subsequently frozen, and specifically, to terminate the agency's unlawful acceptance of the Generally Recognized As Safe ("GRAS") notifications submitted by Hawai'i International Seafood, Inc. (GRAS Notice (GRN) No. 000015).

The ban requested by this Citizen Petition is necessary to prevent serious food safety harms to the public, and preserve consumer confidence in the safety and integrity of the U.S. tuna supply. Moreover, the FDA is obligated to enforce the ban requested under the Federal Food, Drug and Cosmetic Act and current FDA regulations, as a matter of law.

The use of carbon monoxide gas in the packaging of fresh tuna and fresh tuna that is subsequently frozen produces an artificially-enhanced intense, persistent, unnatural red color in tuna that to the naïve consumer can simulate the look of fresh tuna and mask the natural signs of aging and spoilage that consumers depend upon in making safe food choices, including browning and tell-tale odors. Consumers have no way to tell the difference between tuna packaged with carbon monoxide gas that may merely look fresh and safe, and genuinely fresh and wholesome tuna. As a result, carbon monoxide presents serious consumer deception and food safety risks which jeopardize the public health.

2006P-0120

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As set forth more fully in the attached Citizen Petition, EnviroWatch, Inc. urges the FDA to take immediate action to enforce the requested ban on carbon monoxide in fresh tuna packaging, including by withdrawing the agency's unlawfully issued acceptance letters for the above noted GRAS notifications.

Respectfully submitted,

Carroll Cox
President
EnviroWatch, Inc.

EnviroWatch, inc.
www.EnviroWatch.org
PO Box 89-3062, Mililani, HI 96789
envirowatch@envirowatch.org
ph/fx: 808-625-2175

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Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

A. Action Requested

This Citizen Petition is submitted by EnviroWatch, Inc. ("EnviroWatch") under Sections 201, 402, 403, 409, and 721 of the Food, Drug, and Cosmetic Act ("FDCA" or "the Act") and Section 10.30 of the Food and Drug Administration's ("FDA") implementing regulations. EnviroWatch is a non-profit 501(C)(3) organization committed to putting an end to environmental injustice by way of investigating and exposing environmental degradation, habitat destruction, poaching, clear cutting, pollution, animal cruelty, and government waste and abuse. By this Citizen's Petition, EnviroWatch requests that the FDA take immediate action to prohibit the use of carbon monoxide in the packaging of fresh tuna and fresh tuna that is subsequently frozen, including to terminate the agency's unlawful responses to the Generally Recognized as Safe ("GRAS") notification submitted by Hawai'i International Seafood, Inc. ("Hawai'i International"), GRAS Notice (GRN) No. 000015, and taking all such further actions as are necessary to effectively implement and enforce an immediate ban on carbon monoxide in fresh tuna and fresh tuna subsequently frozen, in coordination with USDA Food Safety and Inspection Services ("FSIS"). EnviroWatch advocates the actions requested to prevent serious harm to public health and consumer confidence in the integrity of the U.S. tuna supply.

B. Statement of Grounds

1. Hawai'i International Seafood, Inc.

The FDA has failed to object to a GRAS notification for the unlawful use of carbon monoxide to impart color to frozen tuna products. On March 10, 2000, the FDA

responded to a GRAS notification submitted on behalf of Hawai'i International Seafood,[1] informing the FDA of its GRAS determination for the use of carbon monoxide gas to displace oxygen in fresh tuna that is subsequently frozen. The FDA "no objection" letter expressly recognizes that the functional purpose of the carbon monoxide gas is to "preserve the taste, aroma, texture and color of the frozen seafood."

2. Summary of Argument

This Citizen Petition requests that the FDA take immediate action to prohibit the use of carbon monoxide to displace oxygen in fresh tuna and fresh tuna that is subsequently frozen, including by withdrawing the agency's responses to the unlawful GRAS notification submitted by Hawaii International. The requested action is necessary to prevent serious harm to public health and consumer confidence in the safety and integrity of the U.S. tuna supply. The requested ban of carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen is required under FDCA provisions governing the use of color additives, food additives, and GRAS substances in food.[2]

The use of carbon monoxide in fresh tuna packaging presents serious food safety and consumer deception concerns of the same kinds that historically justified the broad based ban on color additives in fresh tuna products. Carbon monoxide enhances and obscures the natural coloration of tuna that is indicative of freshness and safety, by reacting with the natural myoglobin in tuna to produce carboxmyoglobin, a bright red substance that hides the true colors of tuna, particularly dangerous in anacrobic packaging environments such as those described in the Hawai'i International notification, which potentially allow the proliferation of pathogens but inhibit the growth of aerobic spoilage organisms that provide the tell-tale signs of spoilage upon which consumers rely, in addition to color change, to determine that tuna is no longer safe to consumer. It is well established under federal law that food ingredients are prohibited under conditions that are unsafe, conceal damage or inferiority, or make food appear better or of greater value than it is.[3]

The color-imparting effects of carbon monoxide under the conditions of use in fresh tuna and fresh tuna that is subsequently frozen render the substance an unapproved and prohibited color additive. Neither FDA nor FSIS has the legal authority to permit the use of carbon monoxide in the packaging of fresh tuna and fresh tuna that is subsequently frozen, in the absence of FDA regulations listing carbon monoxide under FDCA section 721. FSIS lacks the authority to make a suitability determination permitting the use of a color additive in tuna, except where it has first been approved by the FDA under FDCA section 721. In the case of carbon monoxide, not only has FDA failed to issue the rules necessary to approve the use in fresh tuna and fresh tuna that is subsequently frozen, but

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[1] Letter from Janice F. Oliver, Deputy Director, Center for Food Safety and Applied Nutrition, to Martin Hahn, Hogan & Hartson (March 10, 2000) ("Agency Response Letter to GRAS Notice No. GRN 000015"), available at http://seafood.ucdavis.edu/guidelines/grn000015.htm (Attachment 1).

[2] 21 U.S.C. 201, 348, and 379(e).

[3] 21 U.S.C. 342(a), (b)(3)-(4), and 601(m).

the agency has also disregarded the explicit prohibition on this very use in fresh tuna under its own food additive regulations.

Section 173.350 of FDA regulations specifies the conditions in which carbon monoxide can be safely used to displace oxygen in food and beverage packaging. This regulation authorizes the use of carbon monoxide for all food and beverages at levels up to 4.5 percent,[4] including in tuna products, with the sole exception that carbon monoxide is categorically prohibited for such use in "fresh meat products."[5] It is well established that the specification prohibiting carbon monoxide in "fresh meat" is required under the FDCA because of serious public health risks attributable to the capacity of carbon monoxide to mask spoilage and promote consumer deception under these conditions.

Because the use of carbon monoxide to displace oxygen in fresh tuna and fresh tuna that is subsequently frozen violates a catalog of provisions of the FDCA and runs afoul of the agency's own regulations, FDA failure to object to the Hawai'i International notifications constitutes unlawful agency action under the Administrative Procedure Act ("APA").[6] The FDA's Agency Response Letters are tantamount to unlawful color additive approvals, for they allow the use of deceptive colorants in violation of the FDCA and in the absence of a required color additive regulation.[7] The agency's failure to follow the statutorily-mandated procedures for color additive approval is an abuse of discretion, for as the Supreme Court has explained, "[i]t is rudimentary administrative law that discretion as to the substance of the ultimate decision does not confer discretion to ignore the required procedures of decisionmaking."[8]

Moreover, the FDA's improper responses expressly allow a use of carbon monoxide that is explicitly prohibited by the agency's own food additive regulation at section 173.350, in violation of the well-settled rule that an agency must follow its own regulations.[9] As FDA has provided no justification for its deviation from that section's prohibition against the use of carbon monoxide-containing packaging gases in fresh tuna and fresh tuna that is subsequently frozen, its Agency Response letters represent arbitrary and capricious agency action. Treating similar situations differently is the essence of arbitrary and capricious action. The Court of Appeals for the District of Columbia Circuit has made clear that "[a]n agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so." For these reasons, the

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[4] 21 C.F.R. 173.350(b)(1).
[5] 21 C.F. 173.350(c).

[6] *See* 5 U.S.C. § 706(2).

[7] *See* 5 U.S.C. § 706(2)(C) & (D)(empowering courts to find unlawful any agency actions in excess of statutory limitations or without observance of procedures required by law).

[8] *Bennett v. Spear*, 520 U.S. 154, 172 (1997).

[9] *See, e.g., Mine Reclamation Corp. v. FERC*, 30 F.3d 1519, 1524 (D.C. Cir. 1994)(characterizing the "well-settled rule that an agency's failure to follow its own regulations is fatal to the deviant action").

FDA's failure to object to the Hawai'i International GRAS notification is unlawful under the APA.

In view of the serious public health issues presented and the requirements of the FDCA and APA, the FDA has no legal authority to permit the use of carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen, and the agency's unlawful responses to the Hawai'i International GRAS notification must be terminated immediately.

3. Applicable Legal Standards

a. Regulatory Framework Governing the Ingredients of Fresh Tuna and Fresh Tuna that is Subsequently Frozen

Under a Memorandum of Understanding between FDA and FSIS implemented in January 2000 ("Meat Ingredients MOU"), the two agencies adopted joint procedures permitting the expedited approval of meat product ingredients, including color additives, food additives, and GRAS substances. The new policy supplanted the longstanding procedures requiring independent and sequential premarket clearance first, by FDA, under the requirements of the FDCA, and second, by FSIS, under the requirements of the FMIA.

Under the FDCA, the FDA has authority for making safety determinations with respect to food ingredients constituting "color additives," "food additives," and substances that are "generally recognized as safe" ("GRAS"), including those intended for use in fresh meat. Under the FMIA, FSIS has authority for making "suitability determinations" concerning ingredients intended for use in fresh tuna and fresh tuna that is subsequently frozen.[10] The FSIS "suitability" evaluation considers consumer protection issues specific to meat products, and may impose limitations on ingredient uses in fresh tuna and fresh tuna that is subsequently frozen that are not required for more general use in food. FSIS guidance provides that, "suitability relates to the effectiveness of the additive in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not result in an unadulterated product or one that mislead consumers."[11] Fresh tuna and fresh tuna that is subsequently frozen products may include only those ingredients that FSIS has expressly authorized.[12]

Under well established FSIS policy, ingredients that function in fresh tuna and fresh tuna that is subsequently frozen to conceal damage or inferiority, or give the

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[10] *See* 65 Fed. Reg. 3330.

[11] *See* Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products," available at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N/Approvalof Ingredients.htm.

[12] 9 C.F.R. 424.21.

appearance the product is better or of greater value than is the case is prohibited.[13] Consistent with this policy, FSIS not only has declined to authorize the use of color additives in fresh tuna and fresh tuna that is subsequently frozen, but also has issued rules explicitly prohibiting such use.

Under FDCA requirements, food ingredients that constitute either "food additives" or "color additives" are prohibited, including in fresh tuna and fresh tuna that is subsequently frozen, except where the FDA has determined the ingredient to be safe under the conditions of intended use and has promulgated regulations authorizing such use.[14] Food ingredients that are established to be GRA under the conditions of intended use are excluded from the FDCA premarket clearance requirements that apply to "food additives" but not from those that apply to "color additives." This means that, for a food ingredient that is established to be GRAS under certain conditions of use, the food ingredient may lawfully be used under such conditions without an authorizing food additive regulation. In contrast, for the same ingredient to be used for color additive purposes, the FDA must promulgate regulations listing the food ingredient for specified conditions of color additive use.

4. The FDCA Prohibits the Use of Carbon Monoxide in Fresh Tuna and Fresh Tuna that is Subsequently Frozen

a. Carbon Monoxide Constitutes an Unapproved Color Additive

Under FDCA section 721, adopted under the Color Additive Amendments of 1960, color additives are prohibited from use in food except under the defined conditions of use specified in by FDA regulations "listing" the particular color additive.[15] Currently, there are no FDA regulations authorizing the use of carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen as required by FDCA section 721.

Section 201(t)(1) of the FDCA defines "color additive" to mean any "substance made by a process of synthesis . . . or otherwise derived, with or without intermediate or final change of identity, ... and when added or applied to a food ... or to the human body ... is capable (alone or through reaction with other substance) of imparting color thereto . . ."[16]

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[13] *See, e.g.*, 21 U.S.C. 601(m); 9 C.F.R. 424.23.

[14] 21 U.S.C. 348 (requiring FDA premarket approval of food additives that are not food contact substances, and authorizing such approval only where there is reasonable certainty that the substance is not harmful under the intended conditions of use); 21 U.S.C. 379(e) (requiring FDA premarket approval and listing of color additives, and authorizing such listing only where the substance is suitable and safe under the conditions of intended use).

[15] 21 U.S.C. 371e.

[16] 21 U.S.C. 321(t)(1).

Under well established FDA policy, "color additives" include substances that impart color through chemical reactions occurring after the substance is applied under the intended conditions of use. FDA has explained that "any chemical that reacts with another substance and causes formation of a color may be a color additive."[17] For example, the FDA has regulated colorless ingredients of sunless tanning lotions and hair dyes as color additives where these substances participate in color imparting reactions with chemicals naturally present in skin and hair during application.[18]

FDA has also has regulated ingredients of food as color additives when the ingredient subsequently participates in color-imparting chemical reactions under the conditions of intended use. For example, ingredients of animal feed intended for consumption by poultry and salmon have been regulated as color additives where the ingredients participate in metabolic reactions which intensify the color of the animal tissues intended for use as human food (e.g., intensified gold in egg yolks and red in salmon fillets).[19]

FDA has recognized that ingredients which impart color to fresh tuna and fresh tuna that is subsequently frozen through chemical reactions with the naturally occurring myoglobin in muscle tissues are appropriately regarded as "color additives" within the meaning of FDCA section 20 I(t)(I). Specifically, in responding to a citizen petition requesting FDA to regulate nitrites in cured meat under FDCA section 721, FDA evaluated the color-imparting effects of nitrite under the "color additive" definition of the Act. While concluding that a "prior sanction" authorizing the use of nitrite in cured meat ultimately nullified the requirements of FDCA section 721 in this context,[20] the FDA determined that nitrites did, in fact, "impart color" within the meaning of the color

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[17] *See, e.g.*, "Color Additives: FDA's Regulatory Process and Historical Perspectives," reprinted from *Food Safety Magazine* (October/November 2003)("Color Additives"), available at http://www.cfsan.fda.gov/~dms/col-regu.html.

[18] *See, e.g.*, 21 C.F.R. 73.2150 (regulating dihyroxyacetone ("DHA") as color additive where the colorless substance, when applied to the skin, reacts with natural skin proteins resulting in the formation of a brown coloring on the skin surface); 21 C.F.R. 73.2396 (regulating lead acetate for use in hair dye as color additive); 21 C.F.R. 73.2110 (regulating bismuth citrate as color additive for use in hair dye).

[19] *See, e.g.* 21 C.F.R. 73.275 (regulating dried algae meal in chicken feed as color additive to enhance the yellow color of chicken skin and egg yolks); 21 C.F.R. 73.295 (regulating tagetes/Aztec marigold meal and extract in chicken feed as color additive to enhance the yellow color of chicken skin and egg yolks); 21 C.F.R. 73.35 (regulating astaxanthin meal in salmon feed as a color additive to enhance the pink to orange-red color of the fish flesh); 21 C.F.R. 73.185 (regulating haematococcus in algae meal in salmon feed as a color additive to enhance the pink to orange-red color of the fish flesh).

[20] The FDA ultimately concluded that the existence of a prior sanction for nitrites established under FDCA section 201(s)(4) provided an adequate legal basis for maintaining the established nitrite policy. The agency concluded that the long history of safe use of nitrites, the enhanced food safety of cured meat products, and consumer familiarity with the distinctive coloration of cured meats justified its decision to uphold the nitrite prior sanction. 45 Fed. Reg. 77043, 77045 (November 21, 1980)(Withdrawal of Proposed Rule). In contrast to the use of nitrites to cure meat, carbon monoxide is not used to cure tuna. To the contrary, carbon monoxide obscures the natural coloration of tuna and gives the appearance of freshness and safety when the natural colors would indicate otherwise.

additive definition, as a result of reactions occurring with myoglobin. The FDA stated, "nitrites 'impart' color ... by reacting with a substance naturally present in the meat to form a third substance that gives the meat a reddish appearance ... The fact that the color given meat by nitrites is similar to the natural color of meat does not warrant the conclusion that the effect of nitrites is merely to 'fix,' rather than 'impart,' color.[21]

Specifically, the FDA determined that, in curing meats, nitrites function to displace water molecules that bind naturally to myoglobin, forming nitric oxide myoglobin, which imparts a red color to the meat. In contrast, in fresh meat, myoglobin naturally binds with oxygen to form oxymyoglobin under ambient conditions. In addition, when cured meat is cooked, nitric oxide myoglobin yields nitrosyl hemochrome, which is pink in color. In contrast, when fresh meat is cooked, oxymyoglobin yields denatured metmyoglobin, which is brown in color. FDA characterized the color imparting effects of nitrites in the context of cooked meat as follows, "[w]ere it not for the use of nitrites, the meat would have a brown color after heating rather than the pink attributed by the presence of nitrosyl hemochrome. Nitrites thus 'impart' color by giving the meat a color after heating that it would not otherwise have."[22]

Like nitrites, carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen imparts color to meat through chemical reactions with the myoglobin naturally occurring in tuna tissues. Myogloblin, which occurs in the a muscle fibers of living animals, is a biological oxygen carrier like hemoglobin, to which it is chemically related.[23] Like the hemoglobin in circulating blood, myoglobin functions to deliver oxygen to the tissues of living animals.[24] Just as the redness of blood varies with the degree to which hemoglobin is oxygenated, so also does the redness of meat vary with the oxygenation of myoglobin. As the myoglobin in fresh cut meat binds naturally with oxygen under ambient conditions, oxymyoglobin is formed, and is responsible for the red color indicative of fresh tuna. Over time, the oxymyoglobin participates in further reactions with oxygen, gradually oxidizing to form metmyglobin, which is browner in color. As oxidation advances, the freshness and safety of fresh meat decreases in relationship to the progressive browning of meat color. Eventually, meat takes on the browned color that consumers have long relied upon to indicate that meat is spoiled and unsafe to consume.

When the oxygen in fresh tuna and fresh tuna that is subsequently frozen is displaced by carbon monoxide, the natural coloration provided by meat pigments is masked. Carbon monoxide binds firmly to myoglobin sites that otherwise would be bound more gently by oxygen, forming carboxymyoglobin in place of oxymyoglobin. Carboxymyoglobin imparts an intense red color to the meat which, in contrast to oxymyoglobin, resists the further reactions with oxygen that would form metmyoglobin.

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[21] Letter from Donald Kennedy, Commissioner of Food and Drugs, to William B. Schultz, Public Citizen Litigation Group, at 12 (June 29, 1979) (Attachment 2).
[22] 44 Fed. Reg. 75659, 75660 (December 21, 1979)(Proposed Rule).

[23] Encyclopedia of Chemical Technology, Vol. 14, at 895 (4th Ed. 1995).

[24] *Id.*, Vol. 16, at 765.

In this regard, carbon monoxide is categorically different from antioxidant color preservatives, which simply inhibit the oxygenation of myoglobin in meat, rather than reacting with the myoglobin to form a new chemical substance.

Just as breathing carbon monoxide endangers living animals through its stubborn displacement of oxygen in circulating hemoglobin, adding carbon monoxide to fresh fish endangers consumers by stubbornly displacing oxygen in tuna myoglobin. Carboxymyoglobin imparts a sustained, artificially bright red color to tuna that simulates the appearance of freshness and safety in tuna when the natural pigments would warn consumers otherwise.

b. The Use of Carbon Monoxide in Fresh Tuna and Fresh Tuna that is Subsequently Frozen Cannot Satisfy the Safety and Suitability Requirements for Color Additive Listing

Section 721(b)(1) of the FDCA authorizes FDA to promulgate a regulation listing a color additive for use in food only "if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.[25] Further, section 721(b)(6) prohibits FDA from listing a color additive for a proposed use if that use "would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act."[26] These provisions operate both independently and in conjunction to prohibit the listing of carbon monoxide for use in fresh tuna and fresh tuna that is subsequently frozen, for this use is neither safe nor suitable precisely because it promotes deception that results in serious food safety concerns.

i. The FDA Has Failed to Demonstrate that Carbon Monoxide in Fresh Tuna and Fresh Tuna that is Subsequently Frozen Would Be Safe Under Actual Conditions of Use

A central intent of Congress in enacting the Color Additive Amendments was to ensure that such additives will be safe under actual conditions of use. The legislative history emphasizes the overarching "safe for use" principle, which is the "scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive."[27] The FDA is required to consider actual conditions of consumer use when evaluating a color additive, and must have concrete evidence that the additive will be used safely. The House Report explains that a color additive may be listed for use only when it is shown that it may be safely used under the conditions prescribed by regulation.[28] Moreover, the regulatory definition of "safe" with respect to

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[25] 21 U.S.C. 379e(b)(1).

[26] 21 U.S.C. 379e(b)(6).

[27] S. Report No. 86-795, at 4 (1959).

[28] *See* H.R. Report No. 86-1761, at 25 (1960) ("House Report").

color additives "means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive."[29]

Neither the FDA nor the FSIS have evidence establishing that carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen is safe under the actual conditions of use. To the contrary, the evidence demonstrates that the use of carbon monoxide in anaerobic packaging systems for fresh tuna and fresh tuna that is subsequently frozen poses genuine food safety risks under real-world conditions. Significantly, even the FDA itself has emphasized the substantial food safety concerns that accompany foods - particularly fresh tuna and fresh tuna that is subsequently frozen packaged with oxygen-displacing gases, such the carbon monoxide-containing modified atmospheres that are the subjects of GRN 000015.[30]

The FDA has devoted a portion of its Food Code to the subject of reduced oxygen packaging ("ROP"). The agency explains that an "anaerobic environment, usually created by ROP, provides the potential for growth of several important pathogens."[31] Specifically, "[i]f products in ROP are subjected to mild temperature abuse, i.e., 5°-12°C (41°-53°F), at any stage during storage or distribution, foodborne pathogens, including *Bacillus cereus*, *Salmonella* spp., *Staphylococcus aureus*, and *Vibrioparahaemolyticus* can grow slowly. Marginal refrigeration that does not facilitate growth may still allow Salmonella spp., Campylobacter spp., and Brucella spp. to survive for long periods of time."[32]

Of particular concern in ROP are *Clostridium botulinum* and *Listeria monocytogenes*. The FDA emphasizes,

> If present, C. botulinum could potentially grow and render toxigenic a food packaged and held in ROP because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable. This is particularly true of psychrotrophic strains of C. botulinum that do not produce tell-tale proteolytic enzymes. Because botulism is potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.[33]

Despite the agency's cautionary language in the Food Code, FDA has failed to exhibit appropriate regulatory concern and vigilance in failing to object to the proposed use of

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[29] 21 C.F.R. 70.3(i).

[30] Food and Drug Administration, Food Code 544 (2005)("ROP [reduced oxygen packaging] which provides an environment that contains little or no oxygen . . . raises many microbiological concerns.").

[31] *Id.* at 546.

[32] *Id.* at 547.

[33] *Id.* at 548.

carbon monoxide in anaerobic packaging for fresh tuna and fresh tuna that is subsequently frozen.

Of even greater concern are consumer handling practices. The FDA observes that "[C]onsumers often cannot, or do not, maintain adequate refrigeration of potentially hazardous foods at home .... Under the best of circumstances, home refrigerators can be expected to range between 5° and 10° C (41° - 50°F)."[34] Thus, while the need for strict temperature control has been emphasized where fresh tuna and fresh tuna that is subsequently frozen is packaged with oxygen-displacing gases, including carbon monoxide, the reality is that the necessary temperature criteria to ensure safety cannot be satisfied under actual conditions of use.

Given the FDA's extreme vigilance over anaerobic packaging in other contexts, it is perplexing that the agency failed to impose strict controls on the use of carbon monoxide and other gases to displace oxygen in fresh tuna packaging. With regard to low-acid and acidified canned foods, where the anaerobic environment can allow *Clostridium botulinum* spores to flourish, the FDA imposes extensive regulations articulating the equipment, controls, manufacturing, processing, and packing procedures which are required to ensure the production of a safe product.[35] Yet in response to carbon monoxide-containing anaerobic packaging for fresh tuna and fresh tuna that is subsequently frozen, which is known to potentially host a wide range of pathogens, including *Clostridium botulinum*, the FDA has imposed no production controls whatsoever, and has failed even to require labeling concerning the need for refrigeration.

It is difficult to conceive of how the controls necessary to ensure the safe use of oxygen-displacing carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen packaging could be established without the promulgation of a food additive regulation, which would provide clear safety criteria to meat packagers using the technology and which would also serve as a touchstone for enforcement efforts to monitor its safe use. Given the realities of temperature abuse in current tuna distribution systems, however, even criteria documented by regulation could not be satisfied under actual conditions of use.

The serious food safety concerns about anaerobic packaging are substantially magnified when carbon monoxide is included among the oxygen-displacing gases. In such packaging systems, not only does the anaerobic environment inhibit aerobic spoilage organisms that provide the indications of spoilage to which consumers are accustomed,[36] but the color imparting effect of the carbon monoxide also masks the

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[34] FDA Food Code, *supra* note 31, at 550.

[35] *See* 21 C.F.R. 108, 113, 114.

[36] *See* Hintlian, C.B. and Hotchkiss, J.H., "The Safety of Modified Atmosphere Packaging: A Review – Do Modified Atmospheres Enhance Pathogenesis But Delay Signs of Spoilage?" 40 Food Technology 70-76 (December 1986), at 75 ("The presence of air in packaged foods supports the growth of aerobic spoilage organisms . . . . In refrigerated products, this noxious warning by spoilage organisms is a critical safety factor since it serves to alert the consumer of temperature abuse and to prevent the consumption of a

natural color change of meat due to aging and deceptively suggests freshness well past the microbial shelflife of the tuna.

It has been extensively documented that appearance - most notably, tuna color - is the primary consideration of consumers in selecting tuna and judging freshness. By imparting a color resembling that of fresh tuna, carbon monoxide in fish packaging deprives consumers of color cues that would indicate spoilage because consumers may not realize that tuna has spoiled when its color remains bright red. Indeed, the FDA itself has acknowledged consumers' reliance on color as a sign of freshness in expressing concerns about the use of carbon monoxide in tuna packaging, and the serious health risk posed when colorants mask the normal signs of spoilage.

While odor has been suggested as an alternative indicator of spoilage of tuna packaged with carbon monoxide,[37] consumers obviously cannot detect the smell of packaged tuna at the point of purchase to determine freshness. Even upon opening the package, however, consumers would not be able to rely upon odor, slime, or other organoleptic indicators of spoilage, because carbon dioxide-containing anaerobic packaging systems such as those that are the subject of the Hawai'i International notifications suppress the growth of aerobic spoilage organisms that produce these signals, while allowing other harmful yet imperceptible pathogens to flourish. Indeed, even the FDA has warned of this significant safety concern accompanying the use of reduced oxygen packaging, cautioning that "the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur."[38] Of particular concern is the fact that consumers would not even be aware that they need to consider freshness criteria other than color or odor, such as "use by" date labeling, because fresh tuna and fresh tuna that is subsequently frozen that is packaged with carbon monoxide is not required to be labeled as such, nor is the carbon monoxide's coloring effect identified. It is important to note that scrombroid poisoning is one of the most commonly reported seafood-related illnesses in the U.S., and results from elevated histamine levels due to decomposition masked by the use of carbon monoxide.[39] Accordingly, carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen presents a serious public health risk because consumers will not be able to rely upon their accustomed indications of spoilage.

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product which may also contain pathogens. Because anoxic MAs can favor the growth of facultative anaerobes and/or obligate organisms, packaging of foods in oxygen-excluded MAs could result in the loss of this safety factor.") (Attachment 3).

[37] *See* Letter from Diane E. Thompson, Associate Commissioner for Legislative Affairs, to Hon. Ray LaHood, Feb. 13, 1998 , at 2 ("Consumers rely on the color of tuna to reflects its state of freshness. A process that inhibits the development of the telltale sensory changes that normally accompany decomposition or spoilage, such as the expected change in the color of the flesh, invite increased exposure to tuna products that are toxic, but not identifiable as such.") (Attachment 4).

[38] FDA Food Code, *supra* note 31, at 546.

[39] *See* L. Cruz, "Carbon Monoxide-Treated Tuna with High Histamine Levels" 2002 FDA Science Forum Poster Abstracts, available at http://www.sushiman.net/ahi/carbon_monoxide1.htm (Attachment 5).

Finally, it cannot be said that cooking the tuna will kill any pathogens and thereby counter any potential safety risks due to the presence of carbon monoxide in an oxygen displacing modified atmosphere for fresh tuna. *Clostridium botulinum* and *Clostridium peifringens*, which, if present, can thrive in such anaerobic atmospheres, are uniquely dangerous in fresh tuna because their toxins are not destroyed by cooking.[40]

Given the record on consumer reliance upon tuna color as an indicator of freshness, the inhibition of other organoleptic indicators of spoilage in modified atmosphere packaging, the documentation of extensive temperature abuse throughout the distribution and handling of fresh tuna, and the inability of cooking to cure the harms of tuna spoilage, FDA has pointed to no evidence demonstrating that no harm will result from carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen under actual conditions of use. Without such evidence, carbon monoxide cannot be shown to be safe and suitable for use in fresh tuna and fresh tuna that is subsequently frozen, and therefore the FDA cannot satisfy the statutory criteria at section 721(b)(1) for listing a color additive.

d. Carbon Monoxide in Fresh Fish Cannot Be Authorized Under FDCA Requirements for Food Additives and GRAS Substances

i. Longstanding FDA Food Additive Regulations Prohibit Carbon Monoxide in Fresh Fish Packaging

The FDA lacks authority to permit the use of carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen under FDCA requirements for food additives. Under well-established FDA food additive regulations specifying the conditions in which carbon monoxide may be used to displace oxygen in food and beverage packaging, such use is expressly prohibited in fresh tuna and fresh tuna that is subsequently frozen. Section 173.350 of FDA regulations prescribes the conditions under which "combustion product gas," including carbon monoxide gas, can be used to displace oxygen in food packaging. The regulation specifies that such food packaging gases "may be safely used" in accordance with defined conditions, including controls to insure that gases "failing to meet the specifications ... be prevented from reaching the food being treated."[41] The rule authorizes the use of carbon monoxide gas in food packaging at levels up to 4.5 percent by volume, provided that "[i]t is used or intended for use to displace or remove oxygen in ... the packaging of beverage products and other food, except fresh meats" and other conditions are satisfied.[42]

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[40] While USDA actively educates consumers that the only way to ensure that meats are cooked to safety is to use a food thermometer, only 2% of consumers report doing so. *See* FSIS, "The Food Safety Educator," available at http://www.fsis.usda.gov/OA/educator3-4.htm; *see* http://www.fightbac.org/cook_facts.cfm.

[41] 21 C.F.R. 173.350(a).

[42] 21 U.S.C. 348.

The FDA is not authorized to pursue this radical departure from longstanding agency and FSIS policy prohibiting colorants in fresh tuna and fresh tuna that is subsequently frozen via response to a GRAS notification. It is a well-established requirement of administrative law that where an agency departs from its prior positions, it must offer a reasoned explanation for its change in view.[43] Such agency action may be deemed arbitrary and capricious "if its rationale does not appear in the administrative record so that its decisionmaking path may reasonably be discerned."[44] That record must demonstrate that the agency has considered all relevant factors. Where the FDA has drastically changed course after reviewing only the GRAS notifications of companies advocating the use of carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen, the agency cannot demonstrate that it has met its burden of considering all relevant factors.[45] Only after promulgating its new policy by means of notice and comment rulemaking on the public record, considering all relevant facts in its policy rationale could the FDA comply with the applicable legal requirements.

ii. Carbon Monoxide in Fresh Tuna and Fresh Tuna that is Subsequently Frozen Cannot Satisfy FDCA Requirements for GRAS Substances

The FDA lacks authority to condone the GRAS status of carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen under the applicable FDCA requirements for GRAS substances. Under FDCA section 201(s), "GRAS" substances are distinguished from and excluded from the scope of the "food additive" definition.[46] Accordingly, under the same specified conditions of intended use, a substance cannot qualify at once as both a "GRAS" substance and a "food additive." The FDCA makes clear that these are mutually exclusive categories, and establishes entirely separate and distinct regulatory requirements for food additives and GRAS substances. As discussed above, in 1962, the FDA promulgated regulations making clear that the use of carbon monoxide to displace oxygen in food and beverage packaging is not GRAS, but rather must be regulated under the food additive provisions of the Act.[47]

More fundamentally, despite the FDA responses to the Hawai'i International notification, the sizable body of scientific evidence makes clear that the safety of carbon monoxide is not "generally recognized" as required by the FDCA. To the contrary, the safety of carbon monoxide in fresh fresh tuna and fresh tuna that is subsequently frozen

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[43] *Department of the Navy v. FLRA*, 962 F.2d 48, 56 (D.C. Cir. 1992); *see also Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir. 1989)("[d]ivergence from agency precedent demands an explanation.").

[44] *Chamber of Argentine-Paraguayan Producers of Quebrancho Extract, et al. v. Holder*, 332 F.Supp. 2d 43, 49 (D.D.C. 2004).

[45] *Id.* at 48.

[46] 21 U.S.C. 321(s).

[47] 21 C.F.R. 173.350.

has been widely challenged in the United States and internationally because of its capacity to mask spoilage and promote consumer deception.

Under the FDA's implementing regulations, the use of a food substance may be established as GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. Under section 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.[48] Under section 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.[49]

For a substance to qualify as GRAS, there must be evidence that the substance is safe under the conditions of its intended use. The FDA has defined "safe" as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use.[50] The FDA has emphasized that a GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use.[51] The "common knowledge" element of the GRAS standard includes two facets: "(1) the data and information relied on to establish the technical element must be generally available; and (2) there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use."[52] The FDA advises that "an ongoing scientific discussion or controversy about safety concerns raised by available data would make it difficult to provide a basis for expert consensus about the safety of a substance for its intended use."[53]

Plainly, the extensively documented controversy in the public literature about the safety of the use of carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen belies any notion that the safety of this use is "generally recognized" among qualified experts. Moreover, a claim of GRAS status for this use of carbon monoxide cannot be maintained in light of the fact that the chemical is banned for use in tuna

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[48] 21 C.F.R. 170.30(b).

[49] 21 C.F.R. 170.30(c) and 170.3(f).

[50] *See* FDA's "Frequently Asked Questions About GRAS" (December 2004), available at http://www.cfsan.fda.gov/~dms/grasguid.html.

[51] 62 Fed. Reg. 18938 (April 17, 1997)(*see* proposed 170.36(c)(4)(i)(C)).

[52] *Id.* at 18942.

[53] *Id.*

packaging across much of the globe, including by Canada, the European Union, Japan and Singapore, because of the same food safety concerns outlined in this petition.[54]

Consideration of the relevant body of evidence makes clear that carbon monoxide in fresh tuna and fresh tuna that is subsequently frozen is not GRAS, and there is substantial scientific evidence substantiating the serious nature of the food safety and consumer deception risks presented.

C. Environmental Impact

The action requested by this petition would result in the termination of the FDA's responses to GRAS notifications and other actions preserving the status quo in conformance with well established law. The action requested is not expected to have significant effect on the quality of the human environment, and is subject to categorical exclusion under 21 C.F.R. 25.30(h). To the best of Petitioner's knowledge, no extraordinary circumstances exist that would require an environmental assessment under 21 C.F.R. 25.21.

D. Economic Impact

Information on the economic impact of the action requested by this petition will be submitted if requested by the Commissioner.

E. Certification

The undersigned certifies that, to the best of his 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 petitioners which are unfavorable to the petition.

For the foregoing reasons, this petition requests that the FDA implement the actions requested to prohibit the use of carbon monoxide in fresh tuna immediately and fresh tuna to be subsequently frozen.

Respectfully submitted,

Carroll E Cox

CARROLL COX
President
EnviroWatch, Inc.

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[54] *See, e.g.*, Julia Moskin, "Tuna's Red Glare? It Could Be Carbon Monoxide," N.Y. Times, Oct. 6, 2004; AVA Food Safety Awareness Programme Statement on Carbon Monoxide Treated Tuna, available at http://www.ava.gov.sg/JAVASCRIPT/carbonMTuna.htm (Attachment 6); Communique from Canadian Food Inspection Agency, Animal Products Directorate, Fish, Seafood and Production, to All Importers of Fish, regarding Fish Treated With Carbon Monoxide, June 17, 1999, available at http://www.inspection.gc.ca/english/anima/fispoi/commun/19990617e.pdf (Attachment 7).