THE WESTON A. PRICE FOUNDATION®
for Wise Traditions in Food, Farming and the Healing Arts
Education ♦ Research ♦ Activism

Division of Docket Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0238

Dear FDA:

The Weston A. Price Foundation submits these comments on Docket No. FDA-2011-N-0238, Preventative Controls for Registered Human Food and Animal Food/Feed Facilities.

The Weston A. Price Foundation (WAPF) is a nonprofit organization with members in every state and internationally. WAPF was founded in 1999 to disseminate the research of Dr. Weston Price, whose studies of isolated nonindustrialized peoples established the parameters of human health and determined the optimum characteristics of human diets. WAPF is dedicated to restoring nutrient-dense foods to the human diet through education, research and activism.

I. Regulation of risk versus "kill steps"

The government's approach to HACCP (Hazard Analysis and Critical Control Points) plans has frequently involved "kill steps" such as pasteurization or irradiation. The FSMA, however, requires a "hazard analysis and risk-based preventive controls" plan, not a HACCP plan. *See* FSMA §103. In assessing HARCP's, the FDA should therefore look at risk reduction rather than kill steps at critical points.

II. Regulations should be scale-sensitive

As included in FSMA, the Tester-Hagan amendment provides that facilities that gross under $500,000 annually and that sell more than half of their products directly to consumers or to local restaurants and retailers are not required to do a HARCP plan if they provide documentation of compliance with state or local food safety laws. *See* FSMA §103(l). **This amendment relieves small, direct-marketing facilities from the burden of a federal HARCP plan.**

There will still, however, be very important differences in scale in the facilities that are subject to the new HARCP requirement. From small wholesale operations to medium-scale direct marketers, there will be numerous facilities subject to the regulations that are a fraction the size of the large processors to which almost all of the foodborne illness outbreaks have been traced. WAPF urges the FDA to include scale-sensitive considerations at every step of the process.

III. General considerations and provisions

WAPF submits these comments on certain traditional, nutrient-dense foods: raw milk cheese, bone broths, and fermented vegetables. These foods play an important role in an optimal diet, and their production should be encouraged in the interests of Americans' short-term and long-term health and vitality. Moreover, these foods have been safely prepared and consumed by people all over the world for centuries. Combining modern principles of hygiene with traditional methods of preparation results in highly safe and nutritious foods.

For all three types of food, the HARCP plan should typically include policies on the following:

Personnel Hygiene

- Handwashing
- Hair restraints and clean uniforms or aprons while handling food
- Exclusion of staff with reported foodborne illness symptoms

Facilities

- Standard operating procedures to address sanitation
- Approved materials for food contact surfaces
- Verification of potable water source
- Layout, design, and work flow to prevent cross-contamination between the initial steps of processing and the final food packaging
- Equipment maintained in a clean and sanitary condition

Controlling physical hazards

- Shielded and/or coated light fixtures in storage and processing areas
- Maintain all storage areas in a sanitary manner
- Packaging of products sufficient to protect from contamination

Section IV, V and VI of these comments provide additional specifics for each type of food.

IV. Raw milk cheese

Consumers choose raw artisan cheese not only for superior taste but also for nutritional value. Raw cheese made from whole milk of pasture-fed cows is a highly nutritious, complete food, providing calcium, phosphorus and a gamut of minerals, a range of B vitamins including B6 and B12, fat-soluble vitamins A, D, E and K and even vitamin C. In raw cheese, these nutrients come in a form that is particularly easy for the body to assimilate. Thus, raw cheese can be considered a complete food, one with superb nutritional advantages. Raw cheese is a "pre-digested" milk product; those with allergies to other milk products can often eat raw cheese, and enjoy its benefits, without problems.

Numerous researchers have reported bactericidal and/or bacteriostatic effects on pathogenic bacteria in cheese because of reduced moisture, low water activity, low pH as the result of organic acid production, salt, competing flora, biochemical metabolites, bacteriocins, and ripening, either singly or in combination.[1] In brief, raw milk cheese can be produced so as to create an environment in which pathogens cannot multiply.

Recommended practices in cheese-making facilities

Microbiological testing:

- Initial phase: establish a microbiological history of raw milk by obtaining test results from supplier(s) or by testing milk produced on site once per week for four weeks for:
  a. Staph Aureus
  b. E. coli O157:H7 (or test for E. coli and treat it as if it were 0157:H7)
  c. Salmonella
  d. Listeria monocytogenes (or test for Listeria and treat it as if it were Listeria Mono.)
  e. Pseudomonas
  f. Campylobacter
- After four weeks, assess the results. If no pathogens have been detected above regulatory levels in a category, reduce the level of testing to semi-annually.
- For those bacteria showing a positive test, develop an action plan to obtain raw milk from a different source, remove cows from the herd, and/or test finished cheese to demonstrate that the potential pathogens are not present or are present in numbers sufficiently low so as not be a risk to public health and safety.
- Maintain records of all required tests on the milk, including antibiotics, total plate count, and somatic cell counts.

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[1] *See, e.g.,* Babel, F. J. 1977. Antibiosis by lactic culture bacteria. J. DAIRY SCI. 60:815–821; Bachmann, H.P., and U. Spahr. 1995. The fate of potentially pathogenic bacteria in Swiss, hard and semihard cheeses made from raw milk. J. DAIRY SCI. 78(3):476–483; Daly, C., W. E. Sandine, and P. E. Elliker. 1972. Interaction of food starter cultures and food-borne pathogens: Streptococcus diacetylactis versus food pathogens. J. MILK FOOD TECHNOL. 35(6):349–357; Dominguez, L., J. F. F. Garayzabal, J. A. Vazquez, J. L. Blanco, and G. Suarez. 1987. Fate of L. monocytogenes during manufacture and ripening of semi-hard cheese. LETT. APPL. MICROBIOL. 34:95–100; Ehlers, J. G., M. Chapparo-Serrano, R. Richter, and C. Vanderzant. 1982. Survival of Campylobacter fetus subsp. jejuni in Cheddar and cottage cheese. J. FOOD PROT. 45:1018–1021; Frank, J. F., and E. H. Marth. 1977. Inhibition of enteropathogenic Escherichia coli by homofermentative lactic acid bacteria in skim milk. J. FOOD PROT. 40:749–753; Gilliland, S. E., and M. L. Speck. 1972. Interactions of food starter cultures and foodborne pathogens: Lactic streptococci versus staphylococci and salmonellae. J. MILK FOOD TECHNOL. 35(5):307–310; Moustafa, M. K., A. A. -H Ahmed, and E. H. Marth. 1983. Behavior of virulent Yersinia enterocolitica duri\ng manufacture and storage of Colbylike cheese. J. FOOD PROT. 46(4):318–320; Reiter, B. 1985. Interaction between immunoglobulins and innate factors such as lysozyme, lactoferrin, lactoperoxidase. J. Schaub (ed.) compos. Physiol. Prop. Human Milk, Proc. Intern. Workshop, Elsevier, Amsterdam pp. 271–284; Ryser, E. T., and E. H. Marth. 1999. Incidence and behavior of L. monocytogenes in cheese and other fermented dairy products. L. monocytogenes, Listeriosis and food safety, 2nd ed. Revised and expanded. L. MONOCYTOGENES IN FERMENTED DAIRY PRODUCTS, pp.411-503; Schaak, M. M., and E. H. Marth. 1988. Interaction between lactic acid bacteria and some foodborne pathogens: A review. CULTURED PROD. J. Nov: 14–20; Spahr, U., and B. Url. 1994. Behaviour of pathogenic bacteria in cheese – A synopsis of experimental data. IDF BULLETIN 298:2–16; Speck, M. L. 1971. Control of foodborne pathogens by starter cultures. J. DAIRY SCI. 55:1019–1022.

- Conduct semi-annual testing on environmental swabs to assess sanitation practices.
- Conduct semi-annual tests on one sample of each type of cheese made:
  a. Chemical tests:
     i. Moisture
     ii. Fat
     iii. Salt
     iv. pH
  b. Microbiological tests:
     i. Salmonella
     ii. Listeria monocytogenes
     iii. E. coli H157:H7
     iv. Staph aureus
     v. Any pathogenic bacteria that had been found in the raw milk used for production

<u>Storage procedures for raw milk:</u>

- Milk held for more than 12 hours should be stored at 41 degrees F or lower
- Milk to be processed in less than 12 hours can be held at up to 55 degrees F

<u>Cheesemaking procedures:</u>

- Maintain specifications on how each type of cheese is made and its final composition, including acceptable ranges for all parameters
- Maintain instructions on the premises for use by those operating the plant, including provisions for when a batch of cheese falls outside the acceptable parameters
- Maintain records of the procedures used in cheesemaking
- Measure and record pH at the following points:
  - Raw milk prior to culture addition
  - At rennet addition
  - At the addition of salt and/or between 5 and 8 hours after rennet is added
  - Prior to brining cheese or at 16-24 hours
  - At 60 days or time of sale

<u>Cleaning practices:</u>

All equipment that comes in contact with the milk or cheese should be:
- Washed manually in such a way as to remove all soil, rinsed, dried and stored, to be sanitized immediately prior to milking, or
- Washed with an adequate CIP system that ensures minimum time and temperature are achieved followed by a sanitizing cycle prior to milking. An adequate CIP includes:
  - Initial rinse with warm water;

    - Alkaline wash at 152 degrees F for 5 minutes, or any combination of temperature and time that achieves the equivalent effect
    - Rinse with clean, potable water
    - Sanitization step
- Where a CIP system is used, after rinsing the equipment all non 3A components are to be fully disassembled to their component parts, washed manually, sanitized, reassembled and put back in place prior to the commencement of the CIP cycle. To clean non-3A components:
    - Disassemble the components and rinse all parts in warm water
    - Wash the component parts in detergent and hot water, using a brush or scrub pad to clean all surfaces
    - Rinse thoroughly in clean, potable water
    - Sanitize all parts and reassemble
- In a manufacturing plant or parlor not cleaned by CIP it is assumed that all items are to be cleaned manually.

Special provision for aging boards

In general, surfaces that come into contact with food should be made of materials such as plastic or stainless steel. However, neither of those surfaces is appropriate for aging cheeses. It is critical to the quality of the cheese that it be aged on **wood**. Wood board should be thoroughly cleaned and sanitized between uses by washing in detergent, rinsing, and then spraying with a disinfectant. Disinfecting options may include a two-step process of vinegar and 3% hydrogen peroxide solutions.

V. Bone Broths

Gelatin-rich bone broth is a traditional food with numerous health benefits. Gelatin is rich in proline, hydroxyproline, and glycine. Research has suggested the proline and glycine should be considered either essential or at least "conditionally essential," which means that under most conditions, the body cannot make enough of these compounds and must get them from food. *See* Irwin, MI, Hegsted DM. *A conspectus of research on amino requirements of man*. J. NUTRITION, 101, 387-429 (1971).

Proline, hydroxyproline, and glycine are important in building the collagenous fibers of cartilage. *See* Resnick, Donald and Niwayama, GEN, DIAGNOSES OF BONE AND JOINT DISORDERS (Philadelphia: WB Saunders, 1988), p. 758. Therapeutic doses of cartilage (which always contains copious amounts of proline and glycine) have been found to dramatically improve rheumatoid arthritis as well as other degenerative joint conditions and inflammatory bowel diseases. *See* Prudden, JF, *The biological activity of bovine cartilage preparations,* SEMINARS IN ARTHRITIS AND RHEUMATOLOGY, III, 4, 287-321 (1974).

Recent studies support the role of gelatin in joint and bone health. A Japanese study reported that a combination of gelatin and casein improved bone mineral content and bone mineral density in mice, greater than the same amount of casein alone. *See* Koyama, et al. *Ingestion of gelatin has* *differential effect on bone mineral density and bodyweight in protein undernutrition*, J. NUTRITION AND SCIENCE OF VITAMINOLOGY, 47, 1, 84-86 (2000). A review of the literature on collagen hydrolysate in the treatment of osteoporosis and osteoarthritis showed positive impacts of gelatin on both pain reduction and inhibition of bone collagen breakdown. *See* Moskowitz, W, *Role of collagen hydrolysate in bone and joint disease*, SEMINARS IN ARTHRITIS AND RHEUMATISM, 30, 2, 87-99 (2000).

Gelatin-rich broths also aid in the digestion of other foods due to their colloidal properties. *See* Pottenger, FM, *Hydrophilic colloid diet*, *Health and Healing Wisdom*, PRICE POTTENGER NUTRITION FOUNDATION HEALTH JOURNAL, 21, 1, 17 (Spring 1997). Gelatin increases the utilization of the protein in wheat, oats, and barley, as well as improving the digestibility of beans and meat proteins. *See* Gotthoffer, NR, GELATIN IN NUTRITION AND MEDICINE (Graylake IL, Grayslake Gelatin Company, 1945), pp. 10-11. Infants fed gelatin-enriched formulas showed reduced allergic symptoms, vomiting, colic, diarrhea, constipation and respiratory ailments than those on straight cow's milk. *See* Gotthoffer, pp. 25-37.

Gelatin's traditional reputation as a health restorer has hinged primarily on its ability to soothe the GI tract. In 2007, a team of researchers published a report that gelatin will protect gastric mucosal integrity in lab rats subjected to ethanol-induced mucosal damages. *See* Samonina G, et al. *Protection of gastric mucosal integrity by gelatin and simple proline-containing peptides,* PATHOPHYSIOLOGY, 2000, 7, 1, 69-73.

Recommended practices in broth-making facilities

When receiving ingredients:

- Record all receiving temperatures.
- Refrigerated products should be received at temperatures of 41 F or lower.
- Frozen products should be received at temperatures of 0 F or lower.
- Shell eggs and shellfish should be received at temperatures of 45 F or lower.
- Inspect package integrity for signs of pest infestation, rust, etc.
- Refuse shipment if deviation occurs.

When storing products:

- Use integrated pest management practices (such as measures to prevent pests from entering facilities, preventing access to food and water, and/or working with a licensed pest control contractor).
- Maintain ingredients at temperature listed in the receiving section, and log storage temperatures at least weekly.
- Segregate all raw and unwashed products from further processed or RTE products.
- Segregate all chemical storage from all foods, packaging materials, and employee facilities.
- All chemicals should be stored in their original containers or clearly labeled if removed from original container.

- Maintain MSDS information readily accessible.

<u>During processing:</u>

- All equipment that comes in contact with the food should be cleaned either with an approved cleaning-in-place (CIP) system or by disassembling to the component parts. If a CIP system is used, any component parts that are not 3A should be disassembled and cleaned.
- Follow accepted thawing procedures and standards.
- Foods should reach 135 F within 4 hours of the start of processing.
- Foods should be cooled from 135 F to 70 F in less than 2 hours, and then cooled from 70 F C to 41 F or cooler within an additional 4 hours.
- Record cooking and cooling temperatures.
- All food contact surface cleaned and sanitized using appropriate chemicals according to manufacturers directions for concentration, contact time, no mixing of chemicals.

<u>During post-processing storage and distribution:</u>

- Foods should be kept at the temperatures listed in the receiving section.
- The final product may be refrigerated or frozen, rather than canned, to better preserve the taste and nutrient value of the product. Canning is not necessary for safety as long as proper temperatures are maintained.

VI. <u>Fermented vegetables</u>

The process of lacto-fermentation was traditionally used to preserve vegetables for long periods without the use of freezers or canning machines. Lactic acid is a natural preservative that inhibits putrefying bacteria. Starches and sugars in vegetables and fruits are converted into lactic acid by the many species of lactic-acid-producing bacteria. These lactobacilli are ubiquitous, present on the surface of all living things and especially numerous on leaves and roots of plants growing in or near the ground.

Like the fermentation of dairy products, preservation of vegetables and fruits by the process of lacto-fermentation has numerous advantages beyond those of simple preservation. The proliferation of lactobacilli in fermented vegetables enhances their digestibility and increases vitamin levels. These beneficial organisms produce numerous helpful enzymes as well as antibiotic and anticarcinogenic substances. Their main by-product, lactic acid, not only keeps vegetables and fruits in a state of perfect preservation but also promotes the growth of healthy flora throughout the intestine. Other alchemical by-products include hydrogen peroxide and small amounts of benzoic acid.

A partial list of lacto-fermented vegetables from around the world shows the universality of this practice. In Europe the principle lacto-fermented food is sauerkraut. Described in Roman texts, it was prized for both for its delicious taste as well as its medicinal properties. Cucumbers, beets and turnips are also traditional foods for lacto-fermentation. Less well known are ancient recipes for pickled herbs, sorrel leaves and grape leaves. In Russia and Poland one finds pickled green tomatoes, peppers and lettuces. Lacto-fermented foods form part of Asian cuisines as well. The peoples of Japan, China and Korea make pickled preparations of cabbage, turnip, eggplant, cucumber, onion, squash and carrot. Korean kimchi, for example, is a lacto-fermented condiment of cabbage with other vegetables and seasonings that is eaten on a daily basis and no Japanese meal is complete without a portion of pickled vegetable. American tradition includes many types of relishes--corn relish, cucumber relish, watermelon rind--all of which were no doubt originally lacto-fermented products. The pickling of fruit is less well known but, nevertheless, found in many traditional cultures. The Japanese prize pickled umeboshi plums, and the peoples of India traditionally fermented fruit with spices to make chutneys.

Lacto-fermentation is an artisanal craft that does not lend itself to industrialization. Results are not always predictable. For this reason, when the pickling process became industrialized, many changes were made that rendered the final product more uniform and more saleable but not necessarily more nutritious. Chief among these was the use of vinegar for the brine, resulting in a product that is more acidic and not necessarily beneficial when eaten in large quantities; and of subjecting the final product to pasteurization, thereby effectively killing all the lactic-acid-producing bacteria and robbing consumers of their beneficial effect on the digestion.

Lacto-fermented vegetables are a very low-risk food. U.S. Department of Agriculture research service microbiologist Fred Breidt has been quoted as saying: "With fermented products there is no safety concern. I can flat-out say that. The reason is the lactic acid bacteria that carry out the fermentation are the world's best killers of other bacteria." Breidt added that there had been no documented cases of food-borne illness from fermented vegetables. *See* Tara Duggan, *Cultivating their fascination with fermentation*, SFGate.com (June 7. 2009) http://articles.sfgate.com/2009-06-07/food/17211395_1_fermented-kimchi-pickles/4

Recommended practices in lacto-fermented-vegetable-making facilities:

- Store vegetables off the ground under sanitary conditions (e.g. prevent rodent infestations, etc);
- Any equipment that comes into contact with the food should be regularly cleaned and sanitized. Equipment should be designed so as to allow reasonable access so as to prevent the build-up of biofilms.
- Prior to bottling, the pH of each batch should be tested. **A pH of 4.6 or lower is the critical evidence of microbiological safety.**

Certain common industrial practices are both unnecessary and even counterproductive for lacto-fermented vegetables:

- The agency should not require chlorination of the vegetables. Chlorination of the vegetables themselves would destroy the beneficial bacteria and enzymes that allow for successful fermentation and that are critical to the quality of the final product.
- The agency should not require pathogen testing. Pathogen testing is unnecessary because of the acidity of the products

PMB 106-380, 4200 Wisconsin Avenue NW, Washington, DC 20016
(202) 363-4394 phone (202) 363-4396 fax info@westonaprice.org www.westonaprice.org

- The agency should not require pasteurization as it is unnecessary as long as the pH levels are 4.6 or below.

VII. Conclusion

It is critical that FDA's new regulations recognize the unique characteristics of raw milk cheese, bone broths, and fermented vegetables. These traditional nutrient-dense foods have excellent track records for safety. Treating these artisanal foods as if they were inherently dangerous would undermine their quality, while not serving the mission of food safety. We urge the agency to learn more about these traditional foods and to approach the regulatory process from that perspective, rather than applying the typical assumptions developed through experience with mass-produced industrial products.

Sincerely,

Sally Fallon Morell
President, Weston A. Price Foundation
PMB 106-380
4200 Wisconsin Ave., NW
Washington, DC 2001