

Exhibit-5
Communication on exempt status for starter
growth media.

**EXEMPT STATUS UNDER FOOD ALLERGEN LABELING
AND CONSUMER PROTECTION ACT OF 2004 FROM
LABELING ON THE FINISHED CHEESE AND OTHER
DAIRY PRODUCTS, THE HYDROLYZED SOY SOLIDS AS AN
INGREDIENT IN THE IMAC STARTER MEDIUM TO MAKE
CHEESE AND OTHER DAIRY PRODUCTS.**

**COMPILED USING THE PAST FIVE YEARS DATA (PRIOR
TO JANUARY 2006) AND PREPARED FOR NOTIFICATION
ON SEPTEMBER 2005.**

**FROM
INTERNATIONAL MEDIA AND CULTURES, INC.
DENVER, COLORADO.**

**TO
F&A DAIRY
NEWMAN, CALIFORNIA**

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 - i) Letter to Mr. George Salfa (Regional Director, USDA , CA.) on May 4th and May 10th from Mr. Venkat Mantha (IMAC, Inc, Denver, CO.)
 - ii) Letter to Mr. John Banks (FDA, Boise, ID.) dated Feb. 6th from Mr. Venkat Mantha (IMAC, Inc., Denver, CO.)
 - iii) Letter to Dr.Reddy (IMAC, Inc.) from Mr. Venkat

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1) Miscellaneous review articles and Patents about the reduced allergenicity in the soy proteins with the various treatments.

STATEMENT OF PURPOSE

International Media and cultures, Inc. (IMAC) based in Denver, Colorado releases this communication. The purpose of this communication is to point out to the cheese and dairy food manufacturers the exempt status evidence under Food Allergen Labeling and Consumer Protection Act of 2004 from labeling on the finished cheese and other dairy products, the hydrolyzed soy solids as an ingredient in the IMAC starter medium and thus in the finished starter culture, to make cheese and other dairy products.

IMAC manufactures starter media and cultures to the dairy industry. We have been in the business since 1982 (company brochure is enclosed). Our manufacturing plants are located in the Midwest region of the country. We are under the supervision of FDA, USDA, Kashurath and other state controlled organizations.

IMAC has been awarded several patents for their outstanding and praiseworthy innovative work. They are the first ever to come up with the idea of reducing the amount of phosphates by substituting with hydrolyzed soy solids in the starter medium without sacrificing the efficacy of the starter. This has reduced the pollution levels in the lakes and rivers and made the regulatory officials and the environmentalists immensely happy. This accomplishment is due to the fact that the hydrolyzed soy has buffering proteins and inherent phosphates.

The use of hydrolyzed soy solids, as an ingredient in the IMAC starter media is just enough to carry on the desired role of buffering and stimulant and to build optimum cell numbers in the liquid starter medium for quantum sufficient usage of starter to make the cheese and other dairy products.

United States Department of Agriculture has limited the starter usage to 3 percent. Hence the amount of hydrolyzed soy solids coming through the starter into the cheese is very minimal. The hydrolyzed soy solids, during the entire process of starter media production, starter making at the cheese plant, cheese making and storage undergoes a series of thermal, enzymatic and acid hydrolysis that makes the proteins to lose their original form into simpler peptides and amino acids, thereby rendering them non-allergenic.

A detailed account of the changes occurring with the hydrolyzed soy solids in the IMAC starter medium and the subsequent use in the starter making and cheese making process is given in the following communication. We have also given the statistical data of the amount of cheese produced in different geographical regions of the country with IMAC starter medium that has hydrolyzed soy as an ingredient, followed by the testimonial from renowned physicians and professors based on the data. We have also enclosed the correspondence with regulatory officials in Idaho, California and Washington D.C. and scientific articles and patents verifying the non-allergenic view of hydrolyzed soy in the wake of various treatments that it undergoes during starter making, cheese making and storage.

EVOLUTION OF STARTERS

Starter cultures are used in the cheese or dairy food manufacturing for the following purposes:

1. Production of lactic acid to assist in the coagulation by rennet
2. Reduction or elimination of pathogenic bacteria
3. Flavor production
4. Proteolysis to improve the digestability and nutritive value
5. Reduction of allergenicity and/or intolerance of food, through proteolysis and/or enzyme hydrolysis of disaccharides.
6. Control of moisture in the cheese
7. Reduction of lactose to reduce lactose intolerance
8. Reduction of simple sugars, to improve baking characteristics of cheese on pizza and other baked foods
9. Starter cultures have therapeutic effect, such as: reduction of cholesterol, cancer in humans, etc.
10. Preservation of the dairy products

Standards of identity of Starter cultures and Media:

The starter cultures used must be safe, suitable, non pathogenic and must be GRAS (generally regarded as safe), according to the code of Federal Regulations.

The starter medium used to grow starter cultures must be made of food grade nutrients and chemicals that support the growth of starter cultures. The following ingredients are commonly used in the starter media in the United States:

1. Non-fat dairy milk---source of protein and carbohydrate.
2. Whey solids---source of protein and carbohydrate.
3. Hydrolyzed vegetable protein (HVP)---source of nitrogen and stimulant and improves cell numbers through protein buffering.

4. Autolyzed yeast extract---source of protein and stimulant (brewers and bakers yeast).
5. Whole cell yeast (generally substrate for growing yeast is not identified, it could be molasses and/or wheat and/or barley)---source of protein and stimulant (brewers and bakers yeast).
6. Soy solids (Hydrolyzed soy solids)---source of nitrogen and stimulant, improves starter cell numbers through buffering.
7. Yeast autolysate---(generally substrate for growing yeast is not identified, it could be molasses and/or barley and/or wheat solids)---source of nitrogen, and stimulant (brewers and bakers yeast).
8. Starch (source not identified)--- thickening agent and suspender.
9. Maltodextrin---bodying agent, nutrient, source of carbohydrate and also suspending agent.
10. Casein (rennet casein and/or acid casein)---source of protein, stimulant, and improves bacterial cell numbers because of protein buffering.
11. Casein hydrolyzate (rennet casein and/or acid casein)---source of protein, peptides, amino acids, and stimulates growth and thus improves bacterial cell numbers.
12. Whey protein concentrate (35, 50, 80% protein)---source of protein and stimulant, and helps to build cell number because of buffering.
13. Acid whey---source of carbohydrate and stimulant.
14. Delactosed whey---source of carbohydrate and stimulant
15. Sodium citrate (chemical)---buffer, chelating agent to reduce calcium to protect bacteria from phage. It also serves as substrate to produce flavor.
16. Disodium phosphate (chemical)---buffer, chelating agent, to reduce calcium to protect bacteria from phage.
17. Monosodium phosphate (chemical)---buffer, chelating agent, to reduce calcium to protect bacteria from phage.
18. Diammonium phosphate (chemical)---buffer, chelating agent to reduce calcium to protect bacteria from phage.

19. Magnesium phosphate (chemical)—buffer, phage protectant, used in internal media.
20. Glycero phosphate (chemical)--- buffer, phage protectant, protects the bacterial cells from acid injury.
21. Lecithin---minute amount used as emulsifier, protects the bacterial cells from acid injury by protecting membranes.
22. Magnesium sulfate (chemical)---used as a minor mineral to stimulate bacteria.
23. Manganese chloride (chemical)---mineral supplement to help the growth of starter bacteria.
24. Guar gum (hydrocolloid)---suspending agent.
25. Ammonia gas---used as a neutralizer liquid starter to limit the acid injury to the bacteria in the liquid starter. Toxic if inhaled.
26. Ammonium hydroxide (50% conc. chemical)---used as neutralizer to reduce the acid injury to the starter bacteria. Toxic if inhaled.
27. Sodium hydroxide (50% conc. chemical)---neutralizer, to reduce acid injury to the starter bacterial cells. It causes severe burns, if spilled on skin.
28. Potassium hydroxide (50% conc. chemical)---neutralizer to reduce acid injury to the starter bacterial cells. It causes severe burns, if spilled on skin.
29. Demineralized whey---nutrient.
30. Whey Permeate---nutrient and mineral supplement, (a waste product produced after removing protein and lactose off the whey).
31. Ferrous sulfate (chemical)---mineral stimulant.
32. Sodium aluminum phosphate (chemical)---buffer, chelating agent, To protect starter bacteria from phage.
33. Capsule encapsulating chemicals-to prevent solubilization at alkaline pH, used in internal media.
34. Silicon dioxide (chemical)---anticaking agent to prevent clumping of the starter media ingredients.
35. Cellulose---anticaking agent to prevent clumping of the starter media ingredients.

36. Corn flour and cellulose----anticaking agent to prevent clumping of the starter media ingredients.
37. Potato starch----anticaking agent to prevent clumping of starter ingredients. Although potato derivatives are not a major allergens, they are registered as allergens.
38. Aluminum silicate----anticaking agent to prevent clumping
39. Hydrochloric acid (chemical)----used to lower pH of the starter.
40. Phosphoric acid (chemical)---used to lower pH of the starter.
41. Citric acid (chemical)---used as a substrate for flavor compounds.
42. Bread and crackers made of wheat and other grains are used as substrates to grow mold starters such as *Penecillium roquefortii* and *camembertii*. The mold hyphae and their spores are then dried and ground along with their substrate and added to the milk or cheese curd to make blue cheese.

None of the above-mentioned starter ingredients except for non- fat dry milk are an approved ingredient to be used in the standard of identity cheeses. Since all these ingredients are allowed and are commonly used in the manufacture of starter cultures, according to 21 CFR there is not set standard of identity for starter cultures or media, and consequently they are exempted from listing on the finished cheese label..

However, U.S.D.A. has set rules not to exceed the usage of starter i.e. 3.0%, to eliminate unscrupulous acts. Apparently at 3.0% level, these non- standard of identity products do not pose a threat. Also, the heat treatments, and fermentation (enzymolysis and acid hydrolysis) given during starter making and subsequent enzyme additions, fermentations, and aging encountered in cheese making, render these ingredients harmless and thus does not warrant declaration on the cheese label. Consequently, none of these ingredients have to be declared on the cheese label. Only declaration to all these ingredients is "cheese cultures". The reason for this type of declaration is very simple. Starter cultures, when grown in milk, or other milk solids such as whey, are susceptible to phage infection. A phage is a virus that kills the bacterial cultures. U.S.D.A. came up

with an invention that was patented and was given as a non-royalty free invention to the industry to protect the starter cultures with use of chelating salts in the starter medium. Unfortunately, these salts are not to be used in the standard of identity products such as cheese etc. However, an exception has been made. However, these chemicals (chelating agents) when used in the starter medium the starter bacterial growth was slow even though they were protecting bacterial cells from phage. Consequently, all other stimulants such as yeast extract, autolyzed yeast extract, whole cell yeast, hydrolyzed vegetable proteins, hydrolyzed soy solids, hydrolyzed casein, etc. were allowed to be used in the starter medium to stimulate the starter bacteria so that they can grow well in the presence of chelating salts such as phosphates and citrates. None of these stimulants were to be used in the standard of identity cheeses as ingredients. To alleviate this, U.S. government made an exception to starter cultures and media and allowed all these ingredients to label as "cheese cultures" on the finished cheese, without having to declare these ingredients. This exception is given only to the starter medium and cultures, because the treatment given to manufacture starter renders these ingredients harmless. Consequently, there are no set standards for the starters in the code of Federal regulations, as long as the ingredients are listed on the starter medium bags for verification by the government agencies and also by the Kashurath organizations.

Genesis of use of Hydrolyzed Soy solids in IMAC Media:

About 10 years ago, dairy industry personnel start complaining about phosphates in the starter medium for two reasons.

1. Reduction of cheese yield because of the emulsification effect of phosphates on casein. Dr. Gary Richardson, Professor of Food Science, at the Utah State University reported this incidence.
2. Since phosphates are used at such high concentrations in the medium, cheese plants kept complaining about their sewer bills. City sewage department charges the plants on the basis of phosphate concentration in the plant discharge. Request came from Ms. Becky Delzer, (Graduate of University of Wisconsin) Manager, Dairy

farmers of America plant at Juda, Wisconsin and others across the country.

At the request of the dairy industry, IMAC started a research project to come up with a solution to reduce the concentration of phosphates in the starter medium and at the same time reduce phage incidence. After few years of research, IMAC found that hydrolyzed soy solids decreases the use of phosphates in the starter medium. At the same time, the usage of yeast extract is also reduced. Several people in the industry prefer hydrolyzed soy solids to yeast solids, ever since FDA announced the soy solids ability to decrease heart diseases, which is a major cause of death in the United States. The reason hydrolyzed soy solids help reduce the high use of phosphates in the medium is that they have inherent phosphate in the matrix. According to the literature and practicing allergy Physicians, yeast extracts, whole cell yeast, and autolyzed yeast extracts etc. have histamine, which excite hyperallergenic reaction. IMAC has thoroughly studied over years, and developed the methods to hydrolyze the soy solids without imparting soy smell to cheese and at the same time making them non-allergenic. IMAC succeeded in accomplishing both and used hydrolyzed soy solids as an ingredient in the starter medium. Excellent quality cheese with significant increase in cheese yields (due to the reduction of chemical-phosphates in the starter growth medium) was made and the failure of starter has been significantly reduced. We have labeled it on our starter medium and we have informed F.D.A. and U.S.D.A. personnel through cheese plant management. Government agencies checked the cheese made with soy as an ingredient in the starter and found no allergens or any health hazardous compounds to warrant declaration on cheese. We were told, as long as we use them in the starter medium, we were in compliance because the treatment we gave to prepare the medium and subsequent fermentation will render the hydrolyze soy proteins non-allergenic. Over 600 million pounds of cheese manufactured and distributed throughout the United States and over 500 million people

consumed the cheese and dairy product made with IMAC starter medium with hydrolyzed soy as an ingredient, with no single complaint in terms of allergens. Thus we have accomplished the decreased use of phosphates in the starter medium to reduce the environmental pollution and to improve the quality of highly functional starter. Lately phosphates have also been blamed for the high rise of osteoporosis disease and for excess obesity in the United States. IMAC made a significant progress in this arena through research and development to reduce usage of phosphates in the starter medium. Hydrolyzed soy solids are only one of the ingredients in IMAC medium. We are listing our starter making procedure, FDA testing, geographic distribution of cheese made with IMAC starter medium with hydrolyzed soy solids etc. It is conceivable from the report that enzyme hydrolyzed soy solids used in the starter medium, and thus used in cheese making are rendered non-allergenic. We are also supplying the references of the plants, and medical authorities we have consulted on this subject. It took us almost 10 years to verify this fact, through laboratory and field trials. We want to thank the Dairy industry asking for help and IMAC is here to help and service industry through research and development, by conforming to the regulations outlined in code of Federal regulations of the United States of America.

MANUFACTURE OF HYDROLYZED SOY SOLIDS AND THEIR SUBSEQUENT USE IN THE STARTER MEDIUM AND CHEESE MAKING PROCESS.

The following are the procedures used in the manufacture of hydrolyzed soy solids.

Procedure # 1

Raw or untoasted defatted soy flour has a protein dispersability index (PDI) of 70-80. The higher the PDI, the better the dispersability of Proteins due to zero denaturation of proteins. The soy flour is then subjected to high heat treatment in its process to make it toasted soy flour. The protein dispersability index on toasted soy flour is 20. At 20 PDI, the dispersability of proteins is less due to the denaturation of proteins. We at IMAC, subject 20 PDI defatted toasted soy flour to enzyme treatment with cellulase and Alcalase (protease) for further denaturation of proteins. Enzyme treated and coated defatted toasted soy flour is thoroughly mixed with other dairy starter growth supporting ingredients such as non fat dry milk, yeast extract, whey solids, glucose, calcium and phosphate buffer salts, along with other minor minerals. It is then bagged into 50 lbs. bags.

The starter medium at the cheese plant is reconstituted to 8 to 15% solids using 70° to 90°F water and then cooked 180 F to 190°F. The media is agitated continuously in the stainless steel tank during heating, cooking and cooling. Generally, it takes two hours to reconstitute 1000 gallons of starter medium. It takes about 45 minutes to one hour for the temperature to reach from 90 F to 140 F. It is to be noted that during reconstitution and heating process of starter medium the enzyme treated and coated defatted toasted soy flour is under going further denaturation of proteins. Cellulase digests the cellulose and hemi-

cellulose and Alcalase is digesting the proteins to smaller peptides. When once the temperature reaches to 150° to 155°F, the enzymes start getting inactivated and the protein is further denatured with heat by holding at 180° to 190°F for 45 minutes to 1 hour. After this high heat treatment for significantly long period of time, the starter medium is cooled to 90° to 110°F depending on the fermentation of the culture employed. The total length of time the media is kept over 165°F is approximately two to two and a half hours. It is quite substantial to denature proteins significantly.

After the medium is cooled to the desired temperature, it is inoculated with starter cultures, (*Lactobacillus bulgaricus* and/or *Lactobacillus helveticus* and/or *Lactobacillus lactis* and *Streptococcus thermophilus* to manufacture Italian type cheeses), lactic cultures (*Lactococcus lactis* var *lactis* and/or *Lactococcus lactis* var *cremoris*) for American type cheeses, and for cream cheese lactic cultures along with *Lactococcus lactis* var *lactis* subspecies *diacetylactis*, and *Leuconostoc citrovorum*. The incubation continues until pH drops to below 5.0 to 4.5. It takes about three to sixteen hours depending on the fermentation process. The concentration of starter bacteria at the end of fermentation process ranges from several hundred million to 10 billion organisms/gram. Generally they are close to 2 to 3 billion organisms per gram of the liquid starter medium. These organisms are highly proteolytic and they further hydrolyze the already hydrolyzed soy proteins rendering them non-allergenic (U.S. patent # 6,855,350). At the end of fermentation process, the culture is cooled to 40° to 60°F and held up to 24 hours to use in the cheese milk. During their storage at 40 F to 60 F, the bacterial proteolytic enzymes continue to hydrolyze the already denatured and hydrolyzed proteins. Also, the proteins are held at low oxidation and reduction (O/R) potential thus rendering them non- allergenic (U.S patent #6190723).

The stored starter is then added to the pasteurized milk. Once again the starter bacteria start to grow in the milk utilizing the already digested starter peptides and amino acids before breaking the milk protein-casein. Also, the milk is coagulated using rennet enzyme. This is also a proteolytic enzyme, further breaking the starter protein into simpler units. Rennet enzyme will also

proteolyzes soy and hydrolyzed soy solids. This has been tested in our laboratory. After the curd is separated from whey, curd amounts to only 10% and the whey is 90%. The cheese is molded at a pH of 5.1 to 5.25. The cheese at this pH has reduced O/R potential. The cheese is then aged from three days to twelve months, depending on the kind of cheese. During the time of storage, the proteins, peptides, peptones are continuously broken down with the aid of added rennet enzymes, bacterial protease, peptidase, and mono and Di amino peptidases. Then, the cheese is ready for consumption. In the case of Italian type and Spanish type cheese, the cheese is baked (600-700 F) or cooked or fried in food preparation, before consumption thus denaturing the proteins further. In the United States, the majority of cheese consumed as an ingredient in other foods. At the end of this intricate process, soy proteins are thermally treated (thermal denaturation), enzyme hydrolyzed (microbial), enzyme hydrolyzed (rennet), and fermented (microbial enzymes) and stewed in acid (lactic acid), thus rendering them non- allergenic.

Procedure #2

Soy proteins are also prepared by reconstituting non- toasted soy flour to 7% solids in 150°F water and at a pH 7.2. The reconstituted soy flour is centrifuged using decanters and the resulting soymilk is subjected to 220°F heat treatment (high heat denaturation). Then, it is evaporated to 18% solids and proteolytic enzymes are added to hydrolyze the protein prior to spray drying. The high heat and enzyme treated spray dried product is then mixed with other starter ingredients and further sprayed with cellulase and protease enzymes. Thereafter, the starter preparation and cheese making is same as outlined in the procedure #1 with toasted soy as an ingredient.

Several billion pounds of cheese and whey obtained from making cheese by using IMAC starter medium have not received any complaints from health department or elsewhere, in the past five years. It goes to prove that allergens are totally inactivated. Several people prefer hydrolyzed soy solids to hydrolyzed casein or autolyzed yeast solids in starter medium to support the growth of starters. According to health authorities, autolyzed yeast solids stimulates the

growth of *Candida* in humans causing candidiosis. In northeastern U.S., soy solids are preferred over casein due to the recent discovery of beneficial aspects of soy solids, like the reduction of heart diseases and reduction of serum cholesterol in humans. Starter medium made using hydrolyzed soy solids, as stimulant does not require significant amount of phosphate salts in the starter medium to inhibit the bacteriophage. The reduction of phosphates in the medium enhanced the cheese yields. Since phosphates contribute to Eutopia, department of natural resources (DNR) objects to the high levels of phosphates in the dairy discharges. IMAC media with soy as an ingredient uses less phosphate and thus less phosphate in the discharge. Also, the starter bacteria grow well and do not get lysed by bacteriophage, which is a plague in the dairy industry.

Soy ingredients in the starter medium, like any other processing aid, go through thermal, enzymatic, and fermentation (enzymatic and acid hydrolysis) process thus rendered non-allergenic. FDA has investigated these facts and checked the cheese made with such an ingredient for allergens and then only allowed us to use this a few years ago without having to declare on the finished cheese product. According to U.S.D.A., the starter usage cannot be over 3% in the cheese making. Generally people use up to 1.0% in the cheese making. It is an infinitesimal amount compared to other ingredients. According to Dr. Steve Taylor, University of Nebraska (Lincoln, NE), the current allergen test is good only for raw material such as flour. After the product is processed, such as hydrolyzation, the allergen can no longer be detected. He also mentioned that the allergen will be significantly diminished. A couple of years ago U.S.D.A. took the samples (cheese) made with our starter for allergen testing. Plants were advised that they would be informed if they find any allergens in the cheese. They have continued to let the plant use the medium without any questions indicating they could not detect any allergens in the cheese. It confirms the findings of Dr. Steve Taylor of University of Nebraska. However, over 500,000,000 pounds of cheese was manufactured in the state of Wisconsin, New York, New Jersey, California, New Mexico, Vermont, and Idaho. All varieties of cheeses were manufactured and they were distributed throughout the United States. We have not received any complaints. Quality Control Director

(Ms. Debbie Barry) at F&A Dairy, Newman, CA, who is using our starter medium with hydrolyzed soy as an ingredient stated that they have not received a single complaint about allergenicity in the cheese in the past five years. According to her records, F&A dairy has manufactured over 200,000,000 pounds of cheese using IMAC starter medium with hydrolyzed soy as one of the ingredients. Also, according to other cheese manufacturers, throughout the U.S., not even a single complaint on cheese came from the field in terms of allergenicity, when IMAC medium with soy solids as one of the ingredients was used to make cheese. The references, contact people and telephone numbers are provided in this communication.

**TESTIMONIALS FROM QUALIFIED PHYSICIANS AND MEDICAL
PROFESSORS.**

Dr. P.K. Vedantan, M.D., a practicing allergy specialist who has an allergy clinic covering State of Colorado, Wyoming, and parts of Nebraska, states that the only way to find out if allergen is present in food (even though the allergenic compound is negative by test) is if a patient responds to that food. Upon analyzing our statistical data, he strongly feels that the allergen must not be present in the cheese. Further more, people who are allergic to soy nuts did not exhibit any signs of allergy when they ate cheese made with IMAC starter with soy as one of the ingredients. Several people have consumed various dairy products made using IMAC starter medium, over a long period of time with no allergic response. Similarly several people who have expressed that they react to soy products with gastric discomfort did not have any such signs of discomfort when they consumed the cheese made with our starter. For that matter, they did not experience any allergy symptoms. Pizza with cheese topping is very popular among young and old alike. It is a very good indicator to check the allergic responses. Since we have not received any complaints it goes to prove that the dairy products made using IMAC starter media with soy as an ingredient did not exhibit any signs of allergies among all age groups (young, middle and old age) in all parts of the United States. Hence, it can be reiterated that the thermal, enzymatic and fermentation treatment of soy rendered them non-allergenic.

Again, according to Dr. P.K. Vedantan, M.D., 600 million pounds of cheese fed to over 500,000,000 people without any allergic complaints, definitely proves, the allergen is inactivated and cannot trigger allergic response in the hypersensitive individual for soy protein. He thought it is more than adequate statistical information to draw an inference. Dr. Vedantan is also a faculty member at

University of Colorado Health Science Center. He can be reached at 970-493-5290. He will be more than happy to discuss this issue.

Dr. Ron Harbeck, Ph.D., Director of Immunology Clinic at the National Jewish Hospital at Denver, Colorado, also stated that 600 million pounds of cheese fed to over 500 million people of different ages, races, gender, without any reported allergic response, definitely goes to prove that thermally treated, enzyme hydrolyzed and fermented soy in starter medium is non allergenic. If not some body should have reacted and reported to the physicians and thus to the local health department. This is a typical protocol followed all over U.S. Dr. Harbeck did extensive research on allergy related issue and has published several articles. His work proved that denatured and/or oxidized protein loses the allergenic properties in mold related allergies. An article is being attached as a reference. Dr. Harbeck can be reached at 303-398-1337, for any discussions on this issue.

Dr. Hari M. Sharma, M.D., FRCP (Fellow of Royal College of Physicians), Professor Emeritus, College of Medicine and Public Health of the Ohio State University, has also attested that soy as one of the ingredients in starter medium, which is thermally treated (180° to 190°F for 30 to 60 minutes), enzyme hydrolyzed using cellulase and protease, and fermented (enzyme plus acid) with dairy starter cultures, and then used in making cheese at the rate of 0.5 to 3.0%, with further enzymolysis due to rennet enzyme used in cheese making, and additional hydrolysis due to second bacterial fermentation during cheese making, followed by aging of cheese from 1 day to 1 year with reduced oxygen conditions will definitely make the soy non-allergenic. He also said that best proof is wide range of people (500 million people) consuming the cheese and dairy products (over 600 million pounds) made with starter containing soy solids as an ingredient (stimulants), with no complaints registered, is a good enough clinical evidence to prove beyond doubt that soy allergens are inactivated when processed as starters through fermentation and then used as ingredient (<3%) in cheese or any other fermented dairy product. He can be reached at 614-879-7898 for further verification.

As a Veterinarian, I, Dr. Reddy (copy of my resume is enclosed for your perusal) was involved in treating canines and felines for various diseases including food allergies. Later as a cheese technologist, I have worked over 35 years with dairy starter cultures, starter medium, and various varieties of cheeses in the United States, United Kingdom, European Economic Community, (Southern Ireland, Germany, France, Italy, Denmark etc.), Eastern Europe, and Mexico, can make an affirmative statement that to the best of my knowledge, enzyme hydrolyzed soy solids using fermentation, enzymolysis and acid hydrolysis, are rendered non-allergenic and does not emit allergic reactions. Further strengthening this statement the concentration of these solids are low in starters and thus going into cheese are small, because the amount of starter used is roughly 0.5 to 1.0 percent. The U.S. government restricts the usage of starter to 3.0%. The solids level in the liquid starter is low, ranging from 7 to 20% and most generally around 8.5 to 12.0%. The concentrations of solids vary because of the amount of buffering required in the liquid starter medium, which in turn depends on the type of fermentation.

**STATISTICAL DATA OF THE AMOUNT OF CHEESE AND OTHER DAIRY
PRODUCTS MADE WITH IMAC STARTER MEDIUM WITH HYDROLYZED
SOY AS AN INGREDIENT.**

The following cheese producers in different geographic locations of U.S. are using IMAC starter medium that has hydrolyzed soy as an ingredient, prior to January 2006 (as of September 2005).

1) F & A Dairy (Newman, CA), U.S.D.A. Inspected plant

- a) Pounds of milk processed per day- **1,500,000**
- b) Number of days of production per week-**6**
- c) Cheese yields → 10% → **150,000 lbs. /day**
- d) **16 inch** pizza will approximately have **6 ounces (oz)** of cheese
- e) According to US standards, 16 inch pizza is consumed by **4 people**
- f) Approximately one pound of cheese is consumed by **11 people**
- g) Annual cheese production at F & A dairy is $150,000 \times 6 \times 52 \rightarrow$ **46,800,000** pounds
- h) Total number of people eating F & A cheese per year $46,800,000 \times 11 \rightarrow$ **514,800,000**
- i) Assuming that each person repeatedly eats pizza once a month
- j) Hence total number of people eating pizza per year that has F& A cheese is → $514,800,000 / 12 \rightarrow$ **42,900,000**
- k) For five years → $5 \times 42,900,000 \rightarrow$ **214,500,000** people.
- l) Hence in five years **234,000,000** lbs of cheese have been consumed by **214,500,000** people in U.S.

F & A Dairy has been making cheese with IMAC systems for the past five years. F & A cheese is distributed throughout the U.S. by national distributors. Hence it is understood that all age groups, race, and gender consume F&A cheese. For

further information please contact: Ms. Debbie Barry (Q.A. Director), F & A Dairy,
Phone: 1-800-626-6580

II) **Cedar Valley Cheese (Belgium, WI)**, U.S.D.A. Inspected plant

- a) Pounds of milk processed per day-**1, 000,000**
- b) Number of days of production per week-**5**
- c) Cheese yields → 10% → **100,000 lbs./day**
- d) **16 inch** pizza will approximately have **6 ounces** of cheese.
- e) According to US standards 16 inch pizza is consumed by **4 people**.
- f) Approximately **11 people** consume **one pound** of cheese.
- g) The annual cheese production at Cedar Valley cheese is $100,000 \times 5 \times 52$
→ **26,000,000 lbs.**
- h) Total number of people eating Cedar Valley cheese → $26,000,000 \times 11$ →
286,000,000
- i) Assuming that each person repeatedly eats pizza once a month
- j) Hence total number of people eating pizza per year that has Cedar
Valley cheese is $286,000,000 / 12$ → **23,833,333**
- k) For 2 years → $23,833,333 \times 2$ → **47,666,666 people**
- l) Hence in 2 years → **52,000,000 lbs.** of cheese is consumed by
47,666,666 people

Cedar Valley cheese has been making cheese with IMAC starter systems for the past two years. Cedar Valley cheese is distributed throughout the U.S. Hence it is understood that all age group, race and gender consume Cedar Valley Cheese. For further information please contact: Mr. Jeff Hiller, Cedar Valley cheese, Belgium, WI, Phone: 920-994-4415.

III) **Tropical Cheese (Perth Amboy, NJ)**, (Spanish cheese), U.S.D.A. Inspected plant

- a) Pounds of milk processed per day-**600, 000**
- b) Number of days of production per week-**5**
- c) Cheese yields → 15% → **90,000 lbs./day**
- d) Total cheese production per year → $90,000 \times 5 \times 52$ → **23,400,000 lbs.**

- e) It is assumed that 6 ounce of cheese is consumed per person per month.
- f) It is assumed that one pound of cheese is consumed by **11 people**
- g) Total number of people eating cheese made by Tropical cheese is-
 $23,400,000 \times 11 \rightarrow \mathbf{257,400,000}$
- h) Hence total number of people consuming food made with cheese made by
 Tropical cheese per year is $\rightarrow 257,400,000/12 \rightarrow \mathbf{21,450,000}$
- i) For five years $\rightarrow 21,450,000 \times 5 \rightarrow \mathbf{107,250,000}$
- j) Hence in five years $\rightarrow \mathbf{117,000,000}$ lbs. of cheese is consumed by
 $\mathbf{107,250,000}$ people

Tropical cheese is using IMAC systems for the past five years. The cheese is distributed nationally and is consumed by all segments of the population. For further information please contact: Ralph Mendez, Tropical cheese, Perth Amboy, NJ, Phone: 1-800-332-4791

IV) Biazzo Dairy (Ridgefield, NJ), U.S.D.A. Inspected plant

- a) Pounds of milk processed per day to manufacture Mozzarella--**200, 000**
- b) Number of days of production per week-**5**
- c) Cheese yields $\rightarrow 10\% \rightarrow \mathbf{20,000}$ lbs./day
- d) Total annual cheese production- $20, 000 \times 5 \times 52 \rightarrow \mathbf{5,200,000}$ lbs.
- e) **16 inch** pizza has **6 ounces** of cheese.
- f) According to US standards 16 inch pizza is consumed by **4 people**.
- g) It is understood that one pound of cheese is consumed by **11 people**
- h) Total number of people eating Biazzo dairy cheese per year $5,200,000 \times 11$
 $\rightarrow \mathbf{57,200,000}$
- i) Assuming that each person repeatedly eat pizza once a month.
- j) So total number of people eating pizza with Biazzo dairy cheese per year-
 $57, 200,000/12 \rightarrow \mathbf{4,766,666}$
- k) For five years $\rightarrow 5 \times 4, 766,666 \rightarrow \mathbf{23,833,330}$
- l) For 5 years $\rightarrow \mathbf{26,000,000}$ lbs. of cheese is consumed by $\mathbf{23,833,330}$
 people

Biazzo dairy has been making cheese with IMAC starter systems for the past 5 years. The cheese is distributed nationally and is being consumed by all

segments of the population. For further information please contact: Alberto Plumacher, Biazzo Dairy, Ridgefield, NJ, Phone: 201-941-6800

V) **Schreiber Foods (Green Bay, WI)**, (Cream cheese), U.S.D.A. Inspected plant, and also State of Wisconsin

- a) Pounds of cream plus milk processed per day-**500, 000**
- b) Number of days of production per week-**5**
- c) Cheese yields → 25% → **125,000**
- d) Total annual cheese production--- $125, 000 \times 5 \times 52 \rightarrow$ **32,500,000 lbs.**
- e) It is assumed that **6 ounces** of cream cheese is consumed per person per month.
- f) One pound of cheese is consumed by **11 people**
- g) Total number of people consuming Schrieber foods cream cheese per year- $32, 500,000 \times 11 \rightarrow$ **357,500,000**
- h) So total number of people consuming food that has cream cheese per year is- $357, 500,000 / 12 \rightarrow$ **29,791,666.**
- i) For five years → $5 \times 29, 791,666 \rightarrow$ **148,958,330 people.**
- j) For 5 years → **162,500,000 lbs.** of cheese is consumed by **148,958,330 people**

Schrieber foods have been using IMAC systems for the past five years. The cheese is distributed and consumed all over U.S. For further information please contact: Kay Wallsten, Schrieber Foods, West Bend, WI, Phone: 262-675-6533

VI) **Tucumcari Cheese (Tucumcari, NM)**, (American style cheese), Inspected by State of New Mexico, Health department.

- a) Pounds of milk processed per day-**250, 000 lbs.**
- b) Number of days of production per week-**4**
- c) Cheese yields → 10% → **25,000 lbs.**
- d) Annual cheese production- $25, 000 \times 4 \times 52 \rightarrow$ **5,200,000 lbs.**
- e) It is assumed **6 ounces** of cheese is consumed per person per month.

- f) One pound of cheese is consumed by **11 people**
- g) Total number of people eating Tucumcari cheese product per year is-5, 200,000x11 → **57,200,000**
- h) Number of people eating food that has Tucumcari product per year is- 57, 200,000/12 → **4,766,666**
- i) For five years → 4,766,666x5 → **23,833,330 people.**
- j) For five years → **26,000,000 lbs.** of cheese is consumed by **23,833,330 people**

IMAC has been supplying its starter systems to Tucumcari cheese for the past five years. The cheese is consumed all over the United States. For further information please contact: Charles Krause, Tucumcari Cheese, Tucumcari, NM, Phone: 505-461-4045

VII) Lucille Farms (Swanton, VT), U.S.D.A. Inspected plant

- a) Pounds of milk processed per day-**1, 000,000**
- b) Number of days of production per week-**5**
- c) Cheese yields → 10% → **100,000 lbs.**
- d) Total annual cheese production → 100,000x5x52 → **26,000,000**
- e) **16 inch pizza will have 6 ounces** of cheese.
- f) According to US standards 16 inch pizza is consumed by **4 people.**
- g) One pound of cheese is consumed by **11 people**
- h) Total number of people consuming Lucille farms cheese per year-26, 000,000x11 → **286,000,000**
- i) Assuming that each person repeatedly consume pizza once a month.
- j) Total number of people consuming pizza that has Lucille farms cheese per year-286, 000,000/12 → **23,833,333**

Lucille farms uses IMAC starter systems in their cheese making process. The cheese is enjoyed all over U.S. For further information please contact: Carl Millerick, Lucille Farms, Swanton, VT, Phone: 802-868-7301

VIII) Suprema Specialties (Manteca, CA), (Ogdensburg, New York), and (Blackfoot, Idaho), U.S.D.A. Inspected plants

- a) Pounds of milk processed per day-**1, 000,000**

- b) Number of production days per week-5
- c) Cheese yields → 10% → **100,000 lbs.**
- d) Annual cheese production → $100,000 \times 5 \times 52$ → **26,000,000 lbs.**
- e) **16 inch** pizza will have **6 ounces** of cheese.
- f) According to US standards 16 inch pizza is consumed by **4 people**.
- g) One pound of cheese is consumed by **11 people**
- h) Total number of people consuming Suprema cheese per year-26,000,000x11 → **286,000,000**
- i) Total number of people consuming pizza with Suprema cheese per year-286,000,000/12 → **23,833,333**

Suprema Specialties used IMAC starter systems in their cheese making process. The cheese was distributed all over U.S., and enjoyed by millions of people all over the country. Suprema is no longer in business hence we could not give any contact person. Their R & D Director was Dr. Reyad Mahmood, who was previously employed by the United States Department of Agriculture.

With the above mentioned statistical data from different cheese manufacturers located in different geographic regions of the country, it is widely perceived that the cheese made with IMAC starter systems that has hydrolyzed soy solids as an ingredient, which undergoes a myriad of treatments during starter making, cheese making and storage is non allergenic. As it always been in the past, the cheese made with IMAC starter systems is exempted from allergen labeling.

STRENGTH IN NUMBERS

We are very proud to make a note that a total of 567,000,000 people from all over U.S. have consumed cheese and other dairy products amounting to 617,000,000 pounds made with IMAC products that has hydrolyzed soy as an ingredient namely Eliminate series, Eradicate series and Enhance series. It should also be noted that the cheese and dairy producers using IMAC products hail from different geographic locations of the country.

PLEASE NOTE: There will be repetition of consumers of cheese and other dairy products made with IMAC products. It emboldens our understanding that the

cheese and dairy products made with IMAC products are non-allergenic. It is due to the fact that if the consumer misses the allergenicity the first time around, he or she cannot miss it the second time. Hence, we emphatically say that the cheese and dairy products made with IMAC products are non-allergenic.

According to U.S. statistics only 2% of the U.S. population have food (and other) allergies. Population of U.S. is approximately 325,000,000. 2% of the population is 6,500,000 people.

A total of 617,000,000 lbs. of cheese is made with IMAC starter that has hydrolyzed soy as an ingredient and is fed to over 567,000,000 people for the past five years.

HYPOTHETICAL SITUATION (FOR ALLERGIC REACTIONS):

At 2 % it is 10,000,000 people

At .1% it is 500,000 people.

At .01% it is 50,000 people.

At .001% it is 5,000 people.

The total number of people at different percentage level having possible allergic reaction with IMAC starter is staggering and palpable and is easily noticed by the health officials in U.S. However, not a single complaint was filed with health department in the past five years. Hence, it goes to prove that soy solids used as an ingredient in the starter medium is rendered non-allergenic statistically as well as test wise when such medium is thermally treated, enzyme hydrolyzed, fermented (microbial proteolysis, and acid hydrolysis), enzyme hydrolyzed with rennet enzyme, microbial proteolysis and acid hydrolysis followed by the reduction of O/R potential in cheese matrix along with aging of cheese

STARTER MEDIUM INGREDIENTS THAT ARE POTENTIAL ALLERGENS.

1) YEAST EXTRACT

In the dairy industry, it is a common practice to use autolyzed yeast and/or autolyzed yeast extract and/or whole cell yeast as one of the ingredients in the starter medium to grow the starter bacterial cultures. The grown starter medium that has yeast derivatives (autolyzed yeast and/or autolyzed yeast extract and/or whole cell yeast) is added to the milk to make cheese. Let us look into the manufacture of yeast extracts. According to some authorities, yeast is an allergen, however, it is not a major allergen (top 8). Yeast is grown on either barley and/or wheat, during the manufacture of beer. The yeast cells are separated from beer (brewers yeast) and are used to manufacture yeast extract. Wheat is used in the beer manufacturing to aid in the head retention and also as a nitrogen source to grow yeast. If wheat is used to grow yeast, the subsequent yeast extract made of such wheat-impregnated yeast must also have wheat allergens. Since wheat is a major allergen (#7), the yeast extract must also be declared as an allergen on the cheese label. Unfortunately, yeast extract is used in every brand of starter medium in the U.S. that is subsequently used to make cheese. Apparently the allergens in the yeast extract must have been rendered non-allergenic with the procedures employed in the culture growth manufacturing such as heat treatment, fermentation (enzymolysis and acid hydrolysis). The same will be true with the hydrolyzed soy solids used as stimulants in the starter medium. Over 600 million pounds of cheese is made and fed to over half a billion people, without any complaints. If hydrolyzed soy solids have to be declared on the label of the finished cheese along with cheese starters cultures,

yeast extract produced by growing yeast on wheat based or wheat contaminated medium must also be declared because wheat is a major allergen. Unfortunately these stimulants, either yeast extract and or hydrolyzed soy solids are essential for the growth of starter cultures in the medium, especially phage resistant medium without which any active starter cannot be made resulting in inferior quality cheese. hence hydrolyzes soy solids are treated just like yeast extract or whole cell yeast, which are used as stimulants in the starter medium, to make cheese.

2) MOLD STARTERS

Similar scenario exists with blue cheese mold starters. Blue cheese is made using approved mold starters such as *Penecillium Roquefort* and *Penicillium Camembertii*. These mold starters are grown on moistened bread made of wheat. After complete growth on bread, the entire bread is crumbled along with mold mycelia and spores. The entire preparation is called mold starter and is used to inoculate either milk or cheese curd to manufacture blue cheese and blue type cheeses such as Roquefort, Gorgonzola, Stilton etc. Camerbert and Brie cheeses are also made using mold as starter. Molds are used in these cheeses to impart characteristic mold flavor. Hence, wheat is a major allergen, such starters must also be declared on the cheese labels. However it is not declared. Also, for the times immemorial, this practice is followed throughout the world and several millions, if not billions of pounds of cheese is made and fed to people. To date nobody complained about allergic responses in these mold fermented cheeses due to wheat solids. Apparently the wheat allergens also rendered non-allergenic with the growth of starter molds and later due to rennet enzyme, and lactic culture fermentation in milk during cheese making and ripening and acid in cheese due to both lactic acid and free fatty acids. Once again it goes to prove that the allergenicity of proteins apparently gets inactivated when they are fermented with dairy starter cultures.

3) LECITHIN

It is a phospholipid. It is one of the starter medium ingredients like yeast extract and hydrolyzed soy solids. It is used in limited amounts. It is an emulsifier. It protects the bacterial cell walls from acid liberated by the bacteria. It is a soy derivative. However, it undergoes all the treatments with the rest of the ingredients of the starter medium and renders non-allergenic.

Dairy starter cultures are associated with plant and vegetable matter in nature. Their proteolytic enzymes apparently inactivate allergens provided the allergenic protein is denatured with heat and/or acid. Hydrolyzed vegetable proteins, soy solids have been used as starter culture growth stimulants. They did not emit allergic reactions, because of denaturation of proteins due to enzymolysis and acid hydrolysis during starter fermentation process as well as the process in the cheeses manufacturing (rennet enzyme, bacterial enzymes, acid production, and O/R reduction potential etc.).

SUMMARY AND CONCLUSIONS

Use of soy solids as an ingredient in the starter medium treated with high heat, enzymes, second heat treatment, fermentation (enzymolysis, acid hydrolysis), enzyme hydrolysis (rennet) in the cheese making, second fermentation in the cheese milk (enzymolysis, and acid hydrolysis) with reduced O/R potential, is safe in terms of lack of allergens. This has been verified by U.S. governmental agencies through periodic testing for allergens and also through field data i.e. 600 million pounds of cheese, (made using IMAC starter with hydrolyzed soy solids as one of the ingredients), fed to over 500 million people of different age groups, gender, races and geographic regions, without any complaints (zero complaints on allergy or any other complaint) for the past 5 years.

The most common symptoms of food allergies are:

1. Skin reactions-Itchy, rash, hives and eczema.
2. Stomach and intestinal reactions-Abdominal pain and bloating, diarrhea, vomiting, gas/flatulence, and cramps.
3. Nose, throat, and lung reactions-Runny nose, sneezing, watery and/or itchy eyes, coughing, wheezing, shortness of breath, and extreme cases of asthma.

It has been conclusively proven, beyond doubt that soy proteins fermented with lactic acid cultures did not exhibit any toxicity or abnormal symptoms in a subculture oral toxicity study. Also, the fermented soy was demonstrated to be non mutagenic in ames test, and did not cause chromosomal damage in mammalian cells in vitro and did not induce micro-nuclei in bone marrow cells in ICR mice tested. In

humans, it did not have any adverse effects when fed as a dietary supplement over a long period of time. This is according to the work of LU, published as an invention with minute details in U.S. patent number 6,835,350. Also, according to this publication, the fermented soy prevented allergy, inflammation, dermatitis and improved immunomodulation by improving the phagocytosis activity of macrophages by 71% in both vitro and vivo. It was also noticed in one of our company staff, whose immune system was greatly improved with the intake of fermented soy. The doctors were pleased with the findings. It was also found that fermented soy inhibited Lipoxygenases and thus act as anti-inflammatory agent, thus modulate immune response to prevent allergy. This is an excellent piece of work to demonstrate beyond doubt that fermented soy proteins not only lose their allergenicity but also improve their ability to reduce allergies. This work ties in good with the observations of U.S.D.A. and F.D.A., who found that the cheese (made with starter with hydrolyzed soy as one of the ingredients), was negative for allergens, consequently they allowed IMAC starter with hydrolyzed soy solids, for the past 5 years, without having to declare soy solids in the finished cheese. Their thinking has always been that if the soy solids are fermented using thermal, enzymatic systems, they will be rendered non- allergenic and thus do not have to be declared on cheese label. Also, 617,000,000 pounds of cheese consumed by over 567,000,000 people in U.S. (although the U.S. population is approximately 300,000,000, the entire population is exposed at least two times in the past five years) for the past five years without any complaints from either people, clinics, or health departments, across the United States, is an excellent statistical indication that allergenicity of soy proteins are inactivated when used as fermentation bases to make cheese. In this connection, please also refer to the article by Reddy and Reddy in terms of the effect of Probiotics on improving the immune modulation and specific mention is made that beneficial starter cultures reduce immune response in allergy. This article is, M.S. Reddy, and D.R.K. Reddy. Proyurveda(Probiotic +

Ayurveda) on curing the acute and chronic disease, without any side effects. Presented at the 23rd AAPI Medical Convention (integrated medicine program), June 15-19, 2005, Houston, TX.

According to medical professional, more than test being negative for allergens in cheese (who have consumed 617 million pounds of cheese), the statistical data of no allergenicity reported in the past five years in 567 million people is more than enough data to conclude, the procedure used to prepare cheese starter culture using IMAC starter made with hydrolyzed soy solids is sufficient to inactivate the allergens and consequently F.D.A. and U.S.D.A. were correct in their testing protocols and thus allowing industry to label it as cheese cultures, without having to declare any other ingredient including the hydrolyzed soy solids (on the finished cheese label). However, starters have to be prepared properly using heat treatment and fermentation. It is a self-controlled prophecy because starters cannot be produced without proper heat treatment and fermentation. Furthermore, U.S.D.A., F.D.A., and State Health departments inspect this area thoroughly.

We conclude our communication by stating that hydrolyzed soy solids, which is one of the ingredients in the IMAC starter medium is rendered **non-allergenic** through various treatments namely thermal, enzymatic and acid hydrolysis that occurs during starter making, cheese making and storage.

To substantiate our conclusion, according to FDA, they have not determined if culture growth media used to make starters are considered part of an ingredient under the Food Allergen Labeling And Consumer Protection Act of 2004 (FALCPA). It means that you do not have to declare hydrolyzed soy solids as an ingredient of the cheese cultures on the finished cheese label. Apparently, Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) does not pertain to starter media and/or cultures and/or enzymes. The latest FDA publication,

published on October 5th 2005, entitled "Guidance for Industry-----
Questions and Answers regarding food allergens, including the Food
Allergen Labeling And Consumer Protection Act of 2004 (FALCPA) does
not require any action with respect to products labeled before January,
1, 2006. We recommend the industry people to read this FDA
communication that will clarify this issue.