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Editorial

Food product development has been both an art as well as science and although how to match flavour or colour or texture etc. can be taught, the original idea for a new product cannot be taught. At times it comes from looking at a similar product and then thinking of a variation in flavour or ingredients. These kinds of new products have been regularly making appearance in Indian markets and we are really good at it. For a long time, until the globalisation, we only saw traditional products for decades with very little changes. Some new varieties of biscuits or savouries did make appearance in the market but it was more an exception than a rule.

When our markets opened, we started seeing a large number of different snack and fast food items and it was an eye opener. Our developers started seeing different possibilities. We even got a few of these giants to Indianise their products with Indian tastes being included. After the initial ice-breaking, we saw a large number of new variations in even in traditional products like papads, farsan, khakhra, etc.

However, variations like cheese flavoured papad, corn flake chivda, etc. may be called slight tweaking of the original product. We have not seen really trailblazing products appearing with bold attempts. If we look at our old traditional Indian food products, there are some amazing examples especially when we go to rural setups. The kind of chutneys and sweetmeats we see is an example. Have we forgotten our capabilities and have been only looking at the West for inspiration?

We have immense diversity of resources in cereals, pulses, milks, fruits, vegetables etc. that we rarely see in the west. In spite of meagre resources they have put up a pretty good show. I have seen some of the sites showing the kind of variations possible with dosas and idlis and rotis. Why some of these do not get into commercial possibilities? I must admit that I have seen in some of the restaurants some bold menu items and I have been tempted but rarely dared to order such strange combinations. On the other hand in buffets I have experimented with something new and have enjoyed it many times.

Some of the events like student competitions in which new recipes were developed. They were quite innovative as well as very nutritious. May be this is what is needed. Students are quite bold and uninhibited unlike us who are oversensitive to criticism. They come up with some really remarkable products that could be truly new products. Industry should seriously look at this possibility developing new products. We might see some really strange combinations which might become as successful as hamburgers and pizzas.

With season’s greetings

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Methodology of Risk Assessment in Foods

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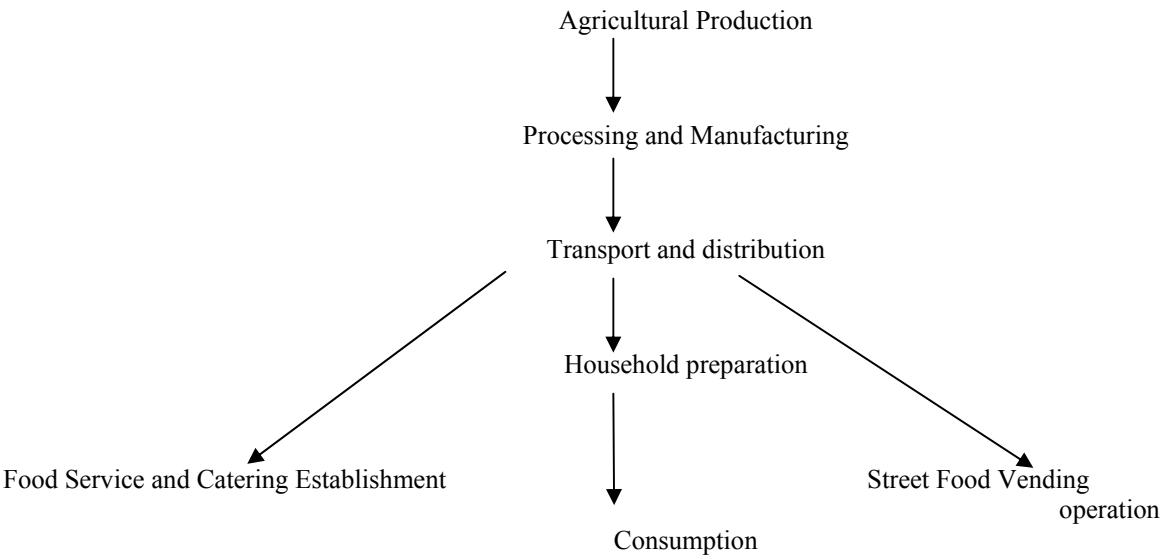
Food Safety is a common concern of all the countries and all the people as everyone being consumer of food is concerned with its safety. Scientists, regulators, food manufacturers and government are interested to identify risk and managing them. Food is a source of nourishment and required for well being. But contaminated food produces illnesses ranging from acute to chronic due to presence of contaminants.

Human exposure to contaminants particularly through diet is a continuous process and not a one-time occurrence or occurring in periodicity. This has resulted in focusing on the safety of food and considering it as one of the basic human right. Contaminants enter into the food chain during any stage.

Model Food Chain



Changing Scenario of Food Safety

Changing agricultural practices globally, international trade requirements and policies, emergence of newer technologies, increased awareness, have created need for global harmonization of food standards. Climatic changes are also contributing to foodborne disease burden. Upto one third of the population of developed countries are affected by food borne diseases. Every year an estimated 2.2 million people are reported to die due to food and waterborne diarrhoeal diseases.

Trade agreements under World Trade Organisation(WTO) and agreement on Sanitary and Phyto Sanitary Measures(SPS) require certain measures, which are based on scientific evidences.

Food Control System

In order to introduce food control measures, food safety assessment and food safety systems have to be developed. Some of the important elements are food standards, laws, policies, regulations; inspection and certification, analytical laboratories; surveillance system and information, education and communication.

Food Contaminants

There are mainly of three types: Physical, chemical and biological.

Physical: Glass, wood, plastic, stones etc.

Biological: Bacteria, viruses, fungi, parasites and biotoxins

Chemical: Pesticide residues, veterinary drug residues, toxic metals, packaging material, dioxins etc

Hazard

According to Codex, a food borne hazard is any agent that can cause an adverse health effect. The contaminants listed above are already known to exist and addressed by food safety control system. A number of new and emerging hazards are posing great threat. Some of these are chemicals formed during food processing. Acrylamide is formed when high carbohydrate containing food is fried in oil at high temperature, eg:- french fries, chips. Acrylamide is converted to glycidamide after ingestion and is a genotoxicant). Some of materials used in packaging are unsafe. Bisphenol A(Bp A) which is present in polycarbonate bottles and tin coatings, is a monomer and used to make polycarbonate and epoxy resins, component of packaging. It is an endocrine disruptor with known toxic properties. Another hazard of recent origin is melamine. Melamine which is used to fraudulently increase the protein content in infant formulas, melamine is a nephrotoxin. Nano particles used in application of nanotechnologies can themselves be toxic. Nano technology is used to assess the shelf life, keeping quality and in other applications.

Risk assessment:

It is the estimation of the probability of the occurrence of adverse events with attendant uncertainty. A structured process is required as risk seldom involves the certainty of direct, measurable observations relevant to human health but involves inference, prediction and uncertainty.

Risk assessment is a component of risk analysis. The other two components of risk analysis are risk management and risk communication. The risk assessment procedure should be able to fulfill it intended purpose. The purpose and scope of risk assessment should be in accordance with risk assessment policy. More importantly it should be based on scientific data relevant to national context. Reference intake levels applicable to country's population must be used in calculations. One may also use benchmark intake or bench mark dose levels. The assessment procedure must take into consideration all the stages in food chain and include sampling inspection and methods of analysis and prevalence of specific adverse health effects in a given population. Uncertainties, constraints which have impact on risk assessment must be considered at each step. Variability in risk estimated must be quantified where ever possible. The procedure must take into account susceptible, vulnerable and special population groups in the country. Acute, Chronic, cumulative as well as combined health effects should be taken in to account.

Steps in Risk Assessment

The risk assessment process is a tiered approach. They are sequentially as follows: a)Hazard Identification b) Hazard characterization c) Exposure assessment d) Risk characterization.

Hazard Identification

It is the identification of known or potential health effects in humans, produced by a contaminant which may be present in a particular food or group of foods. The following points may be considered at this stage namely entry of contaminant at various stages from production to consumption. Even at last stage that is during consumption improper cutlery or non stick kitchenware which are decoated can result in leaching of contaminants into food. The hazard identification may use human studies (epidemiology or volunteer studies), toxicity studies conducted in laboratory animals (acute and chronic) or data from in vitro experiments.

The Organisation of Economic Cooperation and Development(OECD) has taken the initiative and has promoted guidelines for toxicity testing based on Good Laboratory Practice (GLP). The challenge for any method and experimental design used for hazard identification is that it should allow the risk assessor to detect and separate treatment related effects from responses not associated with treatment. Although data from experimental animals or in vitro experiments are not ideal, they may be some of approaches that are available. Alternative methods using *insilco* are also used. Epidemiological evidences linking aflatoxin consumption to liver cancer, nitrosoamines containing foods to aerodigestive tract cancers, consumption of heterocyclic amines formed as a result of browning of food to gastric cancer are some examples where data from humans have been used to identify hazards.

Hazard Characterization

It is the qualitative and if possible quantitative evaluation of the nature of the adverse effects associated with the food contaminants including a dose / response assessment and when possible, the establishment of a safety standard (ADI, TDI or any other comparable toxicological reference) for the intake of contaminants.

A key element in hazard characterization is to establish a dose response profile for the critical effects, that is, the targeted actions identified to be most relevant for human exposure. Usually experiments are conducted in animals to establish a dose level aimed at which No Observed Adverse Effect Level (NOAEL) is observed. Lowest Observed Adverse Effect Level are also used (LOAEL). For certain contaminants for example heavy metals in fishes As Low As Reasonably Achievable(ALARA) may be used. For genotoxic contaminants there is no threshold effect or As Low As Reasonable Achievable(ALARA) and as such ALARP may be used. The characterization process may need several targeted in vitro assays to produce a comprehensive outline of adverse impact. The hazard characterization involves a chain of events namely, internal dose, target organ dose, target organ metabolism and target organ response bridging an external dose of a toxic compound with the ultimate toxicity. Most often the complete knowledge is unavailable, Nevertheless the toxicokinetics (Absorption, Distribution Metoblosim and Excretion, ADME) help in understanding and predicting toxicity. Computer aided physiologically based toxicokinetic (PBTK) models are gaining importance in predicting the internal dose for a particular administration route. PBTK can help in utilizing animal or human data devised from routes different from those most relevant for human exposure.

The characterization should include data or mechanism of action as this has immense impact on the interpretation of dose response findings. Such data may also support results derived from ADME studies. According to conservative approach, genotoxic and carcinogenic agents are assumed to be devoid of dose thresholds, where as for toxic xenobiotics reverse is true. Therefore, exposure to genotoxins is viewed as always imposing a risk, regardless of exposure level. A standard method to derive risk from data on such contaminants is to extrapolate from a given incidence in an experimental setting down to a very low predicted lifetime risk, commonly one in a million. At such a risk level, the exposure is considered virtually safe. For substances showing threshold effects, on the other hand, a critical dose (commonly NOAEL or bench mark dose, BMD) based on toxicity assays is commonly used as a starting point to derive a guidance level at which no significant health risk should occur even when consumed every day. Such values are typically referred to as Acceptable Daily Intake (ADI) or Reference Dose (RfD). Recently a concept named the threshold of toxicological concern (TTC) has gained increasing attention in the regulatory bodies. The TTC concept proposes the establishment of threshold values below which no significant risk should occur. Derivation of such threshold values has been based on carcinogenic data on several additional toxicology endpoints. The Joint FAO/ WHO expert committee on food additives (JECFA) has adopted the TTC principle for the evaluation of flavoring compounds.

Modelling

Modelling on interrelated adverse impacts of chemical contaminants on human health is a challenge. Data merging of relevant information from heterogeneous format into a consistent and rational structure is needed to arrive at meaningful output information. However, even accurate and sophisticated methodologies with most refined evaluation criteria cannot overcome deficits in quantitative or qualitative data to be analyzed. Hence it is imperative to choose a best method suited for understanding a particular issue, endpoint, dose-response relationship, data quality and data quantity. Different quantitative models can be used in dose response - or effect modeling in food risk assessment. The models differ in various aspects, including their ability to address such populations and their requirements regarding the type, amount and qualities of input data. Some models make less of use of proportion of data available, some use only a limited set of experimental data.

Uncertainty Factors

Uncertainty factors are also referred to as safety factors or extrapolation factors. These help to convert and extrapolate experimentally derived toxicological data into risk for human toxicity. The most commonly used uncertainity factor is 100, which can be seen as a product of two factors of 10, accounting for interspecies and inters individual differences. These factors of 10 can be further divided into two parts, corresponding to toxicokinetic and toxico dynamic differences. If chemical specific data is available, each default factor can be replaced with the more appropriate one.

Conventional threshold categories

The standard method for assessing a threshold value for a particular substance is to determine NOAEL. When impossible to establish NOAEL, LOAEL can replace NOAEL. A factor of 10 used to derive NOAEL from LOAEL.

Non-Threshold methods

For some hazards it is considered that there is no threshold limit below which there are no adverse effects. For such contaminant, possible extent of risk is estimated. Quantitative risk assessments can give either estimation or the risk associated with a particular level of exposure or the exposure associated with a particular level of risk. Many mathematical models have been used. Usually extrapolation over some four orders of magnitude is required in order to translate the data from dose-response curves in animal studies to levels relevant for human exposure.

Categorical regression

Categorical regression is a promising statistical tool to estimate potential health risk due to chemical exposures. It gives an estimate of the likelihood that a given category of severity will occur at a given dose level for a given substance. Set of predefined severity categories is assigned to a scheme, qualitatively defining different levels of effect. These levels are No Effect Level (NOEL), NOAEL, LOAEL and severe to lethal effects or frank effect level (FEL). Using these effect levels, it is possible to predict the combined effect severity from different studies and dose effects. (Data from both animals & humans)

In this model both the critical effect and adverse actions may be taken into account. It has been proposed for quantitative dose responses analysis for non cancer toxicity data. Advantage is the possibility to predict the effect for a certain time or concentration interval for which there is no experimental measurement. It also gives information on increasing toxic effect with increasing dose and therefore can be used for estimating potential risk above NOAEL, ADI or RfD.

The Benchmark dose concept

This is a mathematical model fitted to dose response data obtained from traditional toxicological studies in experimental animals. The BMD corresponding to a predefined increase in response, (bench mark response) is calculated from this model.

This concept is an alternative or compliment to the traditional NOAEL approach in risk assessment. The BMD uses more of the information available from the dose response analysis by fitting a mathematical model to the data. A statistical lower bound (95% lower bound of the dose) is referred to as benchmark dose lower confidence limit (BMDC). This value will be used to arrive at an ADI or RfD. Several software packages are available for BMD calculations. To derive BMD a two step process is followed. In the first step the mathematical model is fitted to the data points. The second step is to derive BMD from the effect level defined as the benchmark response level (referred to also as critical effect size, CES) In the first step the problem is availability of enough data points of adequate quality and precision. In the second step the challenge lies in defining the critical level adequately with respect to the biological effect studied. Thus the evaluators should have sound knowledge both in statistics and toxicology. Both quantal and continuous data can be used.

At least three dose groups, preferably more showing different response levels are required. However computer simulations and toxicity studies have shown that study designs with more than the four groups normally reported in toxicological studies are better suited for assessing the BMD. Data of good quality with sufficient number of total data points from number of experimental animals- four dose groups may be used for BMD modeling. Many dose levels and large number of test subjects give a good dose response curve; but from animal ethical point of view this may not be possible.

Probabilistic Hazard Characterization (PHC)

Probabilistic hazard characterization offers another alternative method (a default method based on NOAEL and fixed standard values for extrapolation factors at ADI, TDI or RfD). Probabilistic assessment of ADI requires a range of values(distributions) of which starting point assumes a critical effect size (CES), which includes corresponding uncertainty distribution at which the observation changes are assumed to be non-adverse. Thus data obtained with BMD is preferred over those of NOAEL approach. The associated critical effect dose (CED) is then derived from dose response model of a particular contaminant. The extrapolation factors (EFs) are expressed as distribution and may be obtained from specific experiments / default distribution. The probabilistic ADI is obtained by dividing the CED range with distribution of the individual EF's. This modeling may also be used to estimate possible health effects for a human population at a given exposure level. The dose response information must be obtained from at least three dose groups with different response levels and data must permit fitting of a model. Distribution date for extrapolation factors should be available. If chemical specific information is lacking default distribution may be employed. The major benefit of probabilistic model is that it allows quantification of uncertainty and variability associated with a particular risk assessment.

The distribution obtained indicates the risk level and uncertainty of that assessment. This model also permits estimation of possible health effects in a population for the actual corresponding exposure level. This is a valuable advantage in decision making process and enables comparison of costs for reducing the exposure vis-a-vis the costs for reducing the uncertainty in risk assessment.

Exposure Assessment

It is the qualitative and when possible, quantitative evaluation of the likely intake of the contaminant via food, as well as exposure from all other relevant sources. The amounts ingested depends on levels of contaminants per se including their metabolites if any and the changes they undergo in the food chain at various states. Acute adverse responses occur with single exposure at high levels of contamination. Chronic toxicity is due to prolonged intake of contaminant leading to their accumulation in the body. The exposure is usually addressed to as daily intake level or weekly intake over a life time. The extent of exposure is determined by the amounts of food and water consumed and the concentration of contaminants in these foods. The intakes are expressed as amount ingested per unit time (e.g.: - mg/day) and is related to the body weight. This allows comparison of intakes in human population with the doses used in animal toxicity studies. Risk Managers estimate Margin Of Exposure (MOE) which is the ratio between the exposure level of a specific agent and level considered unsafe. However even with effective modeling method there is no indication to the severity of impact which may differ dramatically between diverse agents even if MOE is Identical.

Dietary Exposure Assessment

The exposure assessment is done by identifying foods of dietary significance for that particular contaminant, the concentrations of contaminants, food intake data for average and most exposed consumers. Data from total diet studies can be also used. The contaminant intakes can be computed from food consumption models. Diet intakes by vulnerable groups can be also used.

Food Balance Sheet (FBS) from surveys can be used. Food available at the household level may be estimated by budget surveys and by consumption surveys. The FBS information on purchases of foods in terms of expenditure is obtained. In household consumption survey the amount of foods and drinks brought into the household is recorded. This survey does not provide information on how food is consumed within the household.

Individual diet survey provides information on actual intake in well defined groups intake in well defined groups of individuals. This data more closely reflect actual consumption. The dietary intake data may be collected by record or recall methods. Record method collects information on current intake over one or more days. Recall methods reflect past consumption, varying from intake over the previous day (24 hour recall) to usual food intake (dietary history or food frequency). Food records, food diaries are kept for a specified time period usually 1-7 days. In the 24 hour recall method the subject is asked by a trained interviewer to recall and describe the kinds and amounts of all foods and beverages ingested during the immediate past, mostly a 24 hour or 48 hour period. Food quantity is assessed by household measures. Food frequency method uses Food Frequency Questionnaire (FFQ). It consists of structural list of individual foods or food groups.

The aim is to assess the frequency with which these items are consumed during a specified time period (eg:- daily, weekly, monthly, yearly). The FFQ may focus on one or several specific chemicals.

Dietary history method

In dietary history method, a trained interviewer assesses an individual's total usual food intake and meal pattern. The respondent is asked to provide information about his / her pattern of eating over an extended period of time (often a typical week) and also to recall the actual foods eaten during the preceding 24 hours. In addition checklist of food usually consumed is also completed. Finally as a crosscheck, the respondent is asked to complete a 3 day estimated record.

Total diet studies

FAO / WHO recommends the use of total diet studies. In this type of study representative samples of widely consumed foods are collected and analysed for the constituents of interest.

The approaches may be

1) Market basket

2) Individual food items and

3) Duplicate portion

In the market basket approach food items which are part of the average diet are purchased, prepared according to standard household procedures and aggregated into a number of food groups. Each food group is analysed for a number of additives, contaminants and nutrients.

In the individual food items approach, a list of foods representing the products most commonly consumed is composed based on national food consumption surveys for several age-sex groups. All selected food items are prepared according to the methods most commonly used and analysed. In duplicate portion or duplicate diet approach, the individual daily diet as consumed is analysed.

The concentration of each contaminant is analysed and calculated by multiplying the value with food item consumed per kg body weight. These values are compared to toxicological reference value (ADI / PTWI).

Risk characterisation

Risk characterisation is the qualitative and / or quantitative estimation, including attendent uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

The risk characterisation is the last step in risk assessment and integrates information from exposure assessment and hazard characterisation and is the basis for correct decision making. The outcome of risk characterisation may be quantitative risk estimate, if any, associated with different levels of exposure. The risk characterisation is an iterative and evolving procedure.

Different approaches have been adopted for risk characterisation of threshold and nonthreshold effects. The hazard characterisation for threshold effect involves the derivation of a level of exposure at or below which there would be no risk to health, If the contaminant is consumed throughout life. A guidance value such as ADI can be derived from NOAEL or other starting point like BMD by using uncertainty factors. For non threshold effects a quantitative hazard estimate can be calculated by extrapolation, usually in a linear fashion from an observed incidence within the experimental dose response range to give a low incidence at a low dose. This traditional approach is based on the assumption that there may not be a threshold dose for effects involving genotoxicity. Alternatively for genotoxic agents exposure should be reduced to as low as reasonably achievable (ALARA) or practicable (ALARP). Risk characterisation considers individuals with average as well as with high exposures. High exposure may be related to life stage, qualitative / quantitative food preferences. Individual differences and susceptibility are important source of variation in response. The variability may be due to other reasons such as dietary habits, nutritional status, physiological status such as pregnancy as well patho physiological states. The patterns of human exposure to chemical in food may be chronic at low levels or short term exposure at high level or any combination thereof. This may result in development of acute reference dose (ARfD) based on short term studies in addition to ADI value based on chronic studies. The significance of intakes above ADI is difficult to assess in terms of quantam of risk since it varies depending on magnitude of excessive intake, its duration, metabolism of contaminant in host and other concomitant conditions. Although intakes above ADI may not always result in adverse health outcome as ADI is based on chronic intake and safety margin, nevertheless erodes the safety margin by the ratio of the ADI to the predicted excess intake.

When risk characterisation is based on animal data it has to be extrapolated to humans taking in with attendent uncertainties, which can be expressed numerically when intake assessment and hazard characterisation are based on mathematical calculations and / or empirical distributions. With the knowledge gained on pharmacogenomics the calculation of uncertainty factor has become complex. There is concern that in case of polymorphisms the default factor may not give adequate protection. In the case of micronutrients which are taken for lifetime, the margin between essential intakes and toxic intakes may vary since both deficiency and over intakes can pose problem and therefore two guidance values may be expressed. Hence the tolerable upper intake level (UL) includes consideration of what does not cause physiological change as well as consideration of the probability of an adverse effect happening at certain specified level of exposure.

Macronutrients which are present in substantial quantities pose their own problem in hazard characterisation as in animal studies, exaggerated amounts may be used which may result in unpalatability or nutritional imbalances. Therefore data from human trials and observational studies are considered more important in terms of identity for identifying adverse effects. Similar to micronutrients the macronutrients may also need more than one guidance value. Margin of safety approach could be used whenever exagerated dose cannot be used.

With more knowledge being gained, the uncertainties can be reduced and can be replaced by contaminant specific information. Such specific studies would require more intense research with higher costs inputs. Improvement and refinements of procedures will pave the path to arrive at more precise risk characterisation.

Report on Workshop on Risk Analysis in Processed Food Manufacture

by Ms. Ummeayman Rangwala, Nutritionist, PFNDAI

PFNDAI has been informally carrying out this activity of making the industry aware of the science behind various aspects of food processing and analyzing the risk factors associated with processed foods and also provided solutions to cope with. However, now it announced to make this activity a more formal one by orgnaising the first workshop on 'RSIK ANALYSIS FOR PROCESSED FOOD AMNUFACTURE' on 15th May 2010 at Hotel Orchid, Domestic airport, Mumbai. This has been only an introductory event, Association looks forward to make it a more regularized and more focused one.

'This is the right time to orgnaise a workshop on risk analysis when globally there has been a concern on safety' pointed out Dr. Henry Chin, Sr. Director, Food Safety & Toxicology, Coca Cola ,USA.

FSSAI is a more science based regulation as compared to PFA further elaborating on the importance of science being reflected in FSSAI, Dr. G.M. Tewari, Chairman of PFNDAI, in his welcome speech addressed the issue of global concern for safety. Safety is not only from the point of consumption but is being dealt from the raw product and at every step of processing to the final consumption and a step ahead i.e. if it has health impact.

Consumers are demanding for a safe food product along with innovations. Many products are entering the market but they are not able to sustain themselves and safety is becoming one of the factors for their failure. For a company to create a good brand value and get consumer confidence the product needs to be backed by researches and studies to prove its safety. Dr. Lewis's presentation further gave an insight into many differences between PFA and FSSAI. The modern food law, FSSAI now not only takes care of food adulteration but it also looks at the safety of the food product and its ingredients. Any representation in PFA was interest based but as FSSAI is a science based regulation, the representation in FSSAI is only by scientific expertise. Also the act says to carry out risk management which shall include the results of risk assessment. This has been the basic core concern for organizing of this workshop.

Today the industry is scared by public & political outcry for safety but this should not scare us off as there might be some reason behind this. Industry should have some scientific results to support its claims and so there arises a need to do risk analysis. Any risk analysis carried out should be robust and the company should have faith and be able to generate faith that their assessment methods are very efficient. Risk analysis comprises of three parts : Risk Assessment, Risk management and Risk communication , so one needs to take all the factors into consideration. Some people have their own personal opinions which cannot be neglected and should be taken into due consideration and here is where risk communication plays a major role. Another important aspect is 'Risk management', it is an important tool for risk procedure and this is tool for regulations too as it is ultimately making this work.

Dr. Sesikeran, Director , NIN inaugurated the workshop and provided an insight into the whole exercise of Risk analysis with a much talked about topic of Bt Brinjal. Risk analysis, he said, needs to be carried out for all the food products. However, there is false sense that traditional food is safer than processed food, this is because we have been using this since a long time and it has been safe, so the history of safe human consumption is a good enough evidence.

Giving an insight into analysis of Bt. Brinjal, he discussed about how we can know the effects of the gene. Out of many concerns one such is if the inserted gene might have affected the minor pathways or produced or suppressed some metabolite which is minute and not detectable. Globally there is compositional analysis carried out where all the known components of a non G.M. variety are compared to the G.M. variety. If there is any minor change in the small metabolic pathway then there would be a variation in the composition of any parameter.

Risk communication is also as important as the risk analysis although these are two different topics but they are equally important and interdependent. If there is a miss communication then the results of risk analysis become more challenging to be considered.

Risk Analysis is a continuous process and so one should not stop analyzing after it has been done once. This is not a one time issue and we should keep doing it every now and then as there is always new addition to our findings and new modes of risk analysis can be seeked to have a better and more efficient risk analysis procedure.

Dr. Henry Chin, said, 'As responsible citizens, scientists and food company we have to make sure we follow the rules & regulations of the land and the product that we provide should be safe for consumption'. Since years, globally there has been lot of research carried out and a good collection of data is available This can be constructive for regulatory approvals, though there might be some extra input required but it would be much better than starting from the scratch. For Novel Foods i.e. one which is not customary or native, there would be exposure assessment required as you need to know the sensitivity of the population.

Dr. Kalpagam Polasa, Deputy Director& Head-Food & Drug Toxicology centre, NIN, presented 'Methodology of Risk Assessment in Foods'. She spoke on the emerging process induced chemical hazards in foods, along with the chemical hazards due to newer technologies and newer adulterants. Today with innovations, more and more nanoparticles are entering the food market, most of these are used as indicators of shelf life but its effect should be known. There needs to be a risk assessment done. When we do risk assessment, we carryout hazard identification, then hazard characterization, exposure assessment and finally risk characterization. Hazard Identification reveals the types of toxicity associated with a particular substance and hazard characterization focuses on the relationship between dose and response that is revealed in these studies. While carrying out Exposure assessment one should know the type and amount of substance present in a given food and the factors effecting their levels and characterization, the amount of food with the chemical substance consumed and the conditions and probability of high consumptions of such food.

Mr. Daniel Geffin , Asst. Country Director, US FDA-Dept. of health and Human services, presented 'Hazard Analysis & Critical Control Points of Sea Foods' wherein he focused on some of the important aspects concerning the presence of salmonella. Like the key HACCP feature , you identify the hazard and then determine how it is controlled and what step in the process you can apply the control. Salmonella in peanut butter is a hazard and this can be minimized either by roasting the peanut before processing or heat the butter, it depends on you, what method you undertake to either eliminate the risk factor or one may not find it feasible and cost effective to completely remove the risk so they may be go only for reduction of risk, one good example is removing the metal pieces by metal detector.

For HACCP certification, one important aspect is record keeping as there needs to be a record to show assessment and monitoring systems and corrective actions must be recorded. One needs to look that same mistake is not repeated, as a lot of time and efforts are lost and also this does not reflect a good risk management system.

Another aspect of great industry concern is the 'Microbial Risk Analysis of Food Products' , this was effectively presented by Ms. Nirmala Ronnie, Asst. Manager-Microbial Approvals, Unilever R&D. She stated the global approach towards risk ranking and the dose for infection for different pathogens may vary, therefore, form the risk assessment point of view their limits in food products differ. Risk assessment can be done in different contexts such as specific pathogen in specific food which are absolute risk assessment. One can also do Relative risk estimate where one pathogen in multiple food or multiple pathogen in one food characterization needs to be done. Geographical risk evaluation is arises when there is introduction of a pathogen in a new region, one of the most recent being the Avian flu.

Different Aspects of Risk Analysis were present by all the speakers with a different perspective , this would surely give the industry a very positive note to look toward the risk analysis and assessment as a positive tool for the development and growth of the food industry not only domestically by also in the Global scenario.

The Luck of the Genes

By Robin Wyers

While environment and diet play a major role in improving chances of living a long and healthy life, role of genes in incredible longevity is much greater than previously assumed. A woman of 106 with right genes, daily smoking two packs of cigarettes for 95 years of her life and a person above 100 with BMI over 40, are just two of the more unusual anecdotes that defy traditional medical logic. Dr. Nir Barzilai, Director, Albert Einstein College of Medicine, NY and his team have isolated 5 or 6 genes linked to longevity from about 30000 human genes. Dr. Barzilai feels there could be 5, 50 or 100 such genes being a small number of the total genes.

He has been researching longevity genes since 1998 focussing on the role of environment and body fat on longevity, and more recently on genetic links between a number of centenarians, many whose parents and grandparents also were centenarians. He explains, “Environment is important for most of us. Our interaction with our environment and mainly food has an 80% role in longevity, the other 20% is down to our genetics.” Two male siblings in animal studies too, one allowed to eat as much as they like, while other on calorie restriction diet (60% for rodents of what their siblings get). The sibling eating more will typically die 50% earlier. Dr. Barzilai noted that this is purely calorie content of food and bears no relation to the type of nutrient consumed whether carbohydrates, fat or proteins. Those eating less will live longer and get less of age-related diseases like cancer and diabetes.

In one study, relation of presence of adipose tissue and longevity was observed. Of those which were allowed to eat as much as they wanted, some had their abdominal visceral tissue removed surgically (which does not grow back) at a young age. This group lived about 30% longer than obese rats that did not undergo surgery. Although they ate more, the absence of fat increased their lifespan.

Another surprising finding was that being overweight (BMI 25 to 30) was found to be the best weight to be in order to have a long life. Advances in medicine, immunisation strategies, hygiene and improved living standards have all had obvious roles in life expectancy. Does overeating leading to overweight actually also be a factor? Dr. Barzilai warns of increased health risks like hypertension and diabetes due to being overweight but being slightly overweight (BMI 28) increases chances of longevity.

In his other significant study, he studied DNA of 500 healthy Ashkenazi Jews, with an average age of 100 to identify common gene traits which explains their longevity. This group’s chances of reaching 100 were 20 times higher than of average person. They also had family history of parent or grandparent living beyond 100. Dr. Barzilai believes that this group’s longevity is 20% influenced by their environment and 80% by their genes. 20 to 30% of this group were obese in the 1950s (BMI over 30). Among this group there was not apparent consumption of special foods, no one was vegetarian or an athlete. One person had BMI of 40 and 20% of the group smoked 2 packs of cigarettes a day for more than 40 years. One woman of 106 smoked 2 packs for 95 years of her life.

Genes that tied the group included two that boost the production of good cholesterol, thereby reducing the risk of heart disease and stroke and another which prevents diabetes. For most people, exercising, eating right food and taking cholesterol pills is important. Dr. Barzilai’s team is trying to identify what is in these genes that is protecting them from the environment which affects the health of all. The team is also trying to study the genes of their children and their effect on longevity.

Pharma industry is interested in genetics area by attempting to develop drugs that mimic genes. However, the focus of their promotion will be prevention of disease rather than longevity e.g. drugs tackling cholesterol. The next step would be to see if they can provide protection against several other age-related diseases. They may not invest in developing drugs against aging as it is difficult to prove and trial with 100,000 people for 30 years would cost $3 billion, with loss of license after just five years. One company is working on CETP (cholesterylester transfer protein) inhibitor drug to tackle cholesterol. Dr. Barzelai thinks that more of such types would be developed.

One company has developed a drug to treat diabetes and maybe protect against age-related diseases. This drug contains resveratrol, the healthy active component in red wine. Resveratrol seems to affect lifespan because it is biologically active and to neutralise the effects of high fat products. Dr. Barzilai was less hopeful about antioxidants from the results of their effect on longevity. He also cautioned that consumers should not take this kind of study as an excuse for poor eating habits and lack of physical activity just because they have a grandmother who is 100 years old.

Extracted from: Food Ingredients First March 2010

Research in Food & Nutrition

New Microalgal Strain Found with High PUFA Levels

Ben-Gurion University of the Negev (BGU) researchers have isolated a microalgal strain which produces large amounts of a polyunsaturated fatty acid that could reduce blood pressure, chronic inflammation and blood cholesterol level, reducing the risk for heart attacks. A research team at BGU's Landau Family Microalgal Biotechnology Lab in the Jacob Blaustein Institutes for Desert Research (BIDR) headed by Prof. Zvi HaCohen, is studying an algal mutant that is capable of accumulating up to 15 percent (of dry weight) of a polyunsaturated fatty acid (PUFA) called DGLA (Dihomo-γ-Linolenic Acid). The new strain, IKG-1, is a freshwater microalga that the researchers believe is the only known plant source capable of producing such significant amounts of DGLA.

"Omega-6 PUFA are necessary as components of brain cell membranes and have various nutritional uses," explains HaCohen, incumbent of the Maks and Rochelle Etingin Chair in Desert Research and rector-elect at BGU. "DGLA is one of these PUFA, but appears in nature only as an intermediate in the biosynthesis of other compounds and does not accumulate to any appreciable concentration. There is no natural source for DGLA and although its beneficial effects are well known, very few clinical studies have been conducted."

The research team also included the director of the Landau Laboratory, Prof. Sammy Boussiba; director of the BIDR Prof. Avigad Vonshak; Dr. Inna Khozin-Goldberg; and Ph.D. student Pushkar Shrestha.

"The significant discovery of the IKG-1 microalgal mutant and its high content of DGLA could impact treatment of life-threatening diseases, such as chronic inflammations, multiple sclerosis and arteriosclerosis," explains Dr. Ora Horovitz, vice president of business development for BGN Technologies, the technology transfer and commercialization subsidiary of BGU.

"Our Microalgal Biotechnology Laboratory continues to be a leading innovator in its work on microalgae and its products harnessing Negev resources, such as brackish water and highly abundant sunlight. BGU is continuing to develop valuable pharmaceuticals and nutraceuticals, as well as biofuels and other potential alternative energy sources."
Nutrition Horizon 4 May 2010
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Algal DHA Omega-3 Improved Memory and Learning in Healthy Adults 55 and Older

The Memory Improvement with Docosahexaenoic acid (DHA) Study (MIDAS) published online this week in Alzheimer's & Dementia: The Journal of the Alzheimer's Association showed that algal DHA improved memory function in healthy aging adults, providing a benefit roughly equivalent to having the learning and memory skills of someone three years younger.

MIDAS is the first large, randomized and placebo-controlled study demonstrating the benefits of algal DHA in maintaining and improving brain health in older adults. The goal of MIDAS was to evaluate the effects of algal DHA on cognitive outcomes in healthy elderly people with a mild memory complaint. The study was funded by Martek Biosciences.

MIDAS found that healthy people with memory complaints who took 900 mg algal DHA capsules for six months had almost double the reduction in errors on a test that measures learning and memory performance versus those who took a placebo, a benefit roughly equivalent to having the learning and memory skills of someone three years younger. The DHA was well-tolerated and subjects taking the DHA also experienced a lower heart rate, providing a significant cardiovascular benefit.

The study population included 485 people 55 and older at 19 U.S. sites who were considered to have age-related cognitive decline. Age-related cognitive decline is defined as decline in cognitive functioning consequent to the aging process that is within normal limits given a person's age. For example, individuals may report problems remembering names or appointments or may experience difficulty solving complex problems.

MIDAS study participants consumed an oral dose of 900 mg per day of algal DHA or a placebo (corn/soy) over the course of six months. The primary endpoint was a cognitive test of memory and learning called the CANTAB Paired Associate Learning (PAL). CANTAB PAL is an assessment of visual memory and new learning, and is a useful tool for assessing patients with age-related memory loss.

"The fear of memory loss and losing brain capacity looms large in the minds of boomers," said renowned neurologist and memory expert, Majid Fotuhi, M.D., Ph.D., author of "The Memory Cure." "But as MIDAS demonstrates in a clinical setting, there are some simple things you can do to maintain and even improve your brain health as you age - like taking 900 mg of algal DHA every day."

DHA is a structural omega-3 fatty acid in the brain that has been shown in epidemiological, preclinical, and now in clinical research to support brain health. Yet, despite DHA's importance, most people eating a Western diet consume low amounts of DHA.

The source of DHA used in MIDAS was a vegetarian and sustainable algal DHA produced by Martek Biosciences, and marketed to consumers under the brand name of life'sDHA. Algal DHA supplements that will enable consumers to easily achieve daily algal DHA intake comparable to the amount used in this study can be found at major drugstores and retailers under the Algal-900 product name and carrying the life'sDHA logo.

"Up to one third of the more than 75 million baby boomers in the U.S. will experience a gradual decline in cognitive function as they age," said Dr. Edward B. Nelson, medical director for Martek and co-author of the study. "MIDAS is significant because it shows for the first time that taking 900 mg of algal DHA daily may have a very meaningful and important impact on cognitive function in the aging population."

"We have known for a long time based on the strong body of epidemiological research that DHA may play an important role in cognitive function, particularly in the aging population," said. Dr. Karin Yurko-Mauro, associate director of clinical research for Martek and project lead of MIDAS. "With MIDAS, we now have clinical evidence to indicate that 900 mg of algal DHA improves memory and learning in aging adults."
Well Sphere 3 May 2010
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Study Highlights Role of Lutein, Zeaxanthin in Visual Performance

On Monday, May 3, 2010, a new study was presented at the Association for Research in Vision and Ophthalmology meeting in Fort Lauderdale that provides further confirmation that the level of macular pigment, comprised of lutein and zeaxanthin from the diet, can positively impact visual performance in individuals with normal eye health and function.

During the baseline testing of 111 healthy young subjects in a one-year, randomized, placebo-controlled, double-blind study, lead author M Dengler and associates measured macular pigment, glare disability, photostress recovery time and contrast enhancement at the Vision Science Laboratory of the University of Georgia. Macular pigment varied widely among the subjects but was significantly and positively correlated with glare disability, photostress recovery time and contrast enhancement. The current study is part of an intervention study, now in progress, which is testing whether supplementing with Lutein and Zeaxanthin leads to improved visual performance by increasing the level of macular pigment.

Glare from bright lights like the sun and high intensity automobile headlights are known to reduce visibility: when too intense glare can cause a temporary loss of vision. Glare is encountered during such normal activities as driving, skiing, boating and golfing. In addition, objects surrounded by blue light have reduced contrast.

NPI Centre 5 May 2010
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Folic Acid Found to Improve Vascular Function in Amenorrheic Runners

A study led by sports medicine researcher Anne Hoch, D.O. at The Medical College of Wisconsin in Milwaukee has found that oral folic acid may provide a safe and inexpensive treatment to improve vascular function in young female runners who are amenorrheic (not menstruating). The study is published in the May 2010 issue of Clinical Journal of Sport Medicine.

While the benefits for women leading an active lifestyle, including running, are profound and well-known, there are serious exercise-associated health risks. Young female athletes who do not eat enough to offset the energy they expend exercising can stop menstruating or develop irregular menses as a consequence. Their resulting estrogen profile is similar to that of postmenopausal women who have low estrogen levels placing the young women at higher risk for early onset heart disease.

There are nearly three million girls in high school sports and approximately 23 million women who run at least six times a week. The prevalence of athletic-associated amenorrhea among these runners is now estimated at 44 percent. A previous study

by Dr. Hoch conducted at Divine Savior Holy Angels High School, Milwaukee, revealed that 54 percent of the varsity athletes were currently or had a history of amenorrhea.

"The earliest sign of heart disease can be measured by reduced dilation in the brachial artery of the arm in response to blood flow. Reduced vascular dilation can limit oxygen uptake and affect performance," says Anne Hoch, D. O., the study's lead author. Dr. Hoch is a professor of orthopaedic surgery and director of the Froedtert & the Medical College Women's Sports Medicine Center.

The current study by Dr. Hoch's research team found that folic acid supplement improved blood flow-mediated dilation in the brachial artery which correlates with increased blood flow to the heart.

Both children and adults require folic acid to produce healthy red blood cells and prevent anemia. Folic acid, also known as vitamin B9, folacin and collate, is the form of the vitamin needed during periods of cell growth.

The researchers recruited 20 female college or recreational runners, ages 18 to 35, who were not on birth control pills and had been running at least 20 miles a week for the past 12 months. At the start of the study, women who were amenorrheic had reduced blood vessel dilation similar to postmenopausal women. Women who were menstruating were included in the control group. Both groups were given 10 mg. of folic acid per day for four weeks. Vascular function returned to normal in the amenorrheic women after folic acid supplementation. Despite supplementation, vascular function remained at normal levels in the control group.

More research is needed to determine the lowest optimal dose of folic acid for athletic amenorrhea which offers the maximum benefit. Folic acid supplementation is important because folic acid may not only decrease cardiovascular risks but also improve athletic performance for these women.
E! Science News 10 May 2010
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New Findings are Further Confirmation of Peptan Hydrolyzed Collagen Benefits on Bone Health

Previous in vivo and in vitro studies carried out with Rousselot Peptan Hydrolyzed Collagen and published in the March 2010 issue of “BONE” have demonstrated the positive effect of this ingredient on bone cells (osteoblasts) and on bone matrix.

At the IOF World Congress on Osteoporosis, Rousselot presented two new in vivo experiments that were aimed at defining the action of Peptan Hydrolyzed Collagen on bone health.

These studies were performed on ovariectomized mice, which are a good model for post-menopause osteoporosis. The mice received a daily intake of Peptan during up to 24 weeks. Bone mineral density (BMD), CTX bone resorption marker and biomechanical properties of the bones were then measured.

The results fully confirm the positive effect of a daily intake of Peptan Hydrolyzed Collagen that had already been observed in previous studies. BMD is significantly higher in mice receiving a Peptan-enriched diet than in the control group which did not receive Peptan. Likewise, the bone resorption marker CTX is lower and bone strength is greater when the mice are fed Peptan.

Finally, these studies have shown that Peptan has a preventive effect on bone loss when given to the mice pre- ovariectomy. Peptan has also demonstrated a similar effect to raloxifene, a pharmaceutical used for post-menopausal osteoporosis.

These new findings confirm the very great advantage of Peptan Hydrolyzed Collagen for bone health and for preventing age-related bone loss.

Nutrition Horizon 11 May 2010
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New Evidence Caffeine May Slow Alzheimer's Disease and Other Dementias, Restore Cognitive Function

Although caffeine is the most widely consumed psychoactive drug worldwide, its potential beneficial effect for maintenance of proper brain functioning has only recently begun to be adequately appreciated. Substantial evidence from epidemiological studies and fundamental research in animal models suggests that caffeine may be protective against the cognitive decline seen in dementia and Alzheimer's disease (AD). A special supplement to the Journal of Alzheimer's Disease, "Therapeutic

Opportunities for Caffeine in Alzheimer's Disease and Other Neurodegenerative Diseases," sheds new light on this topic and presents key findings.

Guest editors Alexandre de Mendonça, Institute of Molecular Medicine and Faculty of Medicine, University of Lisbon, Portugal, and Rodrigo A. Cunha, Center for Neuroscience and Cell Biology of Coimbra and Faculty of Medicine, University of Coimbra, Portugal, have assembled a group of international experts to explore the effects of caffeine on the brain. The resulting collection of original studies conveys multiple perspectives on topics ranging from molecular targets of caffeine, neurophysiological modifications and adaptations, to the potential mechanisms underlying the behavioral and neuroprotective actions of caffeine in distinct brain pathologies.

"Epidemiological studies first revealed an inverse association between the chronic consumption of caffeine and the incidence of Parkinson's disease," according to Mendonça and Cunha. "This was paralleled by animal studies of Parkinson's disease showing that caffeine prevented motor deficits as well as neurodegeneration "Later a few epidemiological studies showed that the consumption of moderate amounts of caffeine was inversely associated with the cognitive decline associated with aging as well as the incidence of Alzheimer's disease. Again, this was paralleled by animal studies showing that chronic caffeine administration prevented memory deterioration and neurodegeneration in animal models of aging and of Alzheimer's disease."

Key findings presented in "Therapeutic Opportunities for Caffeine in Alzheimer's Disease and Other Neurodegenerative Diseases":

* Multiple beneficial effects of caffeine to normalize brain function and prevent its degeneration
* Caffeine's neuroprotective profile and its ability to reduce amyloid-beta production
* Caffeine as a candidate disease-modifying agent for Alzheimer's disease
* Positive impact of caffeine on cognition and memory performance
* Identification of adenosine A2A receptors as the main target for neuroprotection afforded by caffeine consumption
* Confirmation of data through valuable meta-analyses presented
* Epidemiological studies corroborated by meta-analysis suggesting that caffeine may be protective against Parkinson's disease
* Several methodological issues must be solved before advancing to decisive clinical trials

Mendonça and Cunha also observe that "the daily follow-up of patients with AD has taught us that improvement of daily living may be a more significant indicator of amelioration than slight improvements in objective measures of memory performance. One of the most prevalent complications of AD is depression of mood, and the recent observations that caffeine might be a mood normalizer are of particular interest."
Medical News Today 18 May 2010
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Multivitamins Can Improve Mood and Mental Performance

Research into a vitamin and mineral supplement by academics at Northumbria University shows it improves mood and mental performance while also reducing stress, mental tiredness and fatigue in healthy males.

The effects of multivitamins are most often researched in the elderly. This is one of very few studies to assess the relationship between supplementation with vitamins/minerals and psychological functioning in healthy groups of non-elderly adults. This study shows how a proprietary multivitamin and mineral supplement improves mood and mental performance while also reducing stress, mental tiredness and fatigue in healthy males.

In a randomized, double-blind and placebo-controlled study, 215 men in full-time employment aged between 30 and 55 were given either a proprietary multivitamin or a placebo for a period of 33 days.

The two groups were tested at the beginning of the study and at the end with a battery of mood, stress and health questionnaires and with physical and mental tasks that included mental arithmetic (counting backwards in 3s or 7s from a random number).

The multivitamin was a B complex, vitamin C and minerals product known as Berocca which is manufactured by Bayer Consumer Care, the sponsors of the study.

Prior to treatment, there were no significant differences between the placebo and multi-vitamin/minerals groups in performance or ratings for any of the study outcomes. However, after 33 days supplementation the multivitamin/minerals group reported significantly improved ratings of general mental health, reduced subjective stress and increased ratings of ‘vigour’, with a strong trend towards an overall improvement in mood. Task performance, in terms of the number of correct serial-3 subtractions throughout the six repetitions of the cognitive tasks, and serial-7s during the first repetition, was also improved.

This was accompanied by reduced ratings of ‘mental tiredness’ before and after the intense mental processing and a trend towards reduced ‘mental fatigue’. The placebo group showed no significant changes.

The effects of multivitamins are most often researched in the elderly, and very few studies have assessed the relationship between supplementation with vitamins/minerals and psychological functioning in healthy groups of non-elderly adults.

“Overall, these results suggest that improving nutritional status, by supplementation if necessary, may be beneficial to males within the general population as a whole,” says Northumbria University’s Professor David Kennedy, who led the study.

“The assumption was made here that the men tested enjoyed typical nutritional status. However, the very fact of being able to improve mood, ratings of mental health and vigour and aspects of task performance by simple supplementation with B vitamins, Vitamin C and minerals indicates that the cohort must have been suffering from less than optimal micronutrient status at the outset.”

“We know that optimum functioning of the central nervous system is dependent on a wide range of micronutrients, and there is a wealth of evidence from epidemiological studies that clearly suggest a relationship between micro-nutrients and psychological functioning.

“Vitamin C for example is the brain’s most prevalent antioxidant and is found at its greatest concentrations in neuron-rich areas.”
Hawkes’ Health Forum 17 May 2010
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Calcium in Early Life May Prevent Obesity Later

There’s no denying that people need calcium for strong, healthy bones. But new research from North Carolina State University suggests that not getting enough calcium in the earliest days of life could have a more profound, lifelong impact on bone health and perhaps even obesity than previously thought.

During an 18-day trial involving 24 newborn pigs, the researchers documented markedly lower levels of bone density and strength in 12 piglets fed a calcium-deficient diet compared to 12 piglets that received more calcium. Not only that, but when researchers looked at certain stem cells in bone marrow, they found that many of these cells in the calcium-deficient piglets appeared to have already been programmed to become fat cells instead of bone-forming cells.

Because these programmed mesenchymal stem cells replicate to provide all the bone-forming cells for an animal’s entire life, very early calcium deficiency may have predisposed the piglets to have bones that contain more fat and less mineral. That could make those pigs more prone to osteoporosis and obesity in later life, said Dr. Chad Stahl, an associate professor of animal science who led the study.

In a longer-term study that Stahl plans to begin this month, the researchers will look at whether that’s the case: By conducting a longer feeding trial, the scientists will be able to see if the changes persist through sexual maturity, which occurs for pigs at around eight months of age.

The researchers are using pigs as a model for human health because pigs and humans are similar when it comes to bone growth and nutrition. Pigs are one of the few animals known to experience bone breaks related to osteoporosis, Stahl said.

One of the most surprising findings of the 18-day feeding study was that while the calcium-deficient pigs had substantially lower bone strength and density, blood tests didn’t indicate any difference in levels of the hormonal form of vitamin D, which regulates the amount of calcium circulating in the blood of older children and adults. Stahl said this suggests that calcium regulation in newborns isn’t dependent on vitamin D.

Stahl thinks the research is relevant to the infant food industry and suggests the significance of the nutritional status of breastfeeding mothers. It also points to a need for greater emphasis in very early life on bone health, not just during those times when children are growing most rapidly.

“While the importance of calcium nutrition throughout childhood and adolescence is well-recognized, our work suggests that calcium nutrition of the neonate may be of greater importance to lifelong bone health, due to its programming effects on mesenchymal stem cells,” Stahl reported at the recent Experimental Biology 2010 meeting in Anaheim. “It also points to a potential paradigm shift in which health professionals might want to begin thinking about osteoporosis not so much as a disease of the elderly, but instead as a pediatric disease with later onset.

“For me,” Stahl said, “the biggest message is that calcium nutrition, or mineral nutrition as a whole, needs to be a priority from day one. Early life nutrition is setting children up physiologically for the rest of their lives.”
Eurekalert 13 May 2010
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Researchers Discover Additional Benefit of Vitamin A

Vitamin A is critical to maternal health and child survival, yet in most developing countries Vitamin A deficiency is a leading cause of blindness and increased child mortality. The Johns Hopkins Bloomberg School of Public Health has long been a leader in vitamin A research, and scientists at the School recently discovered a link between offspring lung function and maternal vitamin A supplementation. The results are published in the May 13, 2010, issue of the New England Journal of Medicine.

"Children of mothers who received vitamin A supplementation before, during and after pregnancy had significantly improved lung function when compared to those whose mothers received beta-carotene supplementation or placebo," said lead author of the study, William Checkley, MD, PhD, assistant professor in the Division of Pulmonary and Critical Care of the Johns Hopkins School of Medicine with a joint appointment in the Bloomberg School's Department of International Health. "Lung function of offspring in mothers who received maternal vitamin A supplementation improved by about 40 ml versus those whose mothers received a placebo. This represents an approximately 3 percent increase in lung function. Furthermore, the magnitude of effect observed in this study is slightly greater than that associated with preventing exposure to parental smoking in school-age children."

Vitamin A deficiency affects nearly 190 million preschool-age children worldwide and is the underlying cause of 650,000 early childhood deaths annually. To examine the effect of antenatal vitamin A supplementation on lung function, researchers revisited a cohort of children ages 9 to 13 in rural Nepal whose mothers were randomized to receive vitamin A, beta-carotene or a placebo. Using a portable pneumatochometer, offspring lung function was measured. They found that children whose mothers received vitamin A instead of a placebo had a significantly greater forced expiratory volume at one second (FEV1) and a greater forced vital capacity (FVC), while children whose mothers received beta-carotene instead of a placebo had similar FEV and FVC.

"Improved lung function was likely specific to supplementation received in utero because this population of children was subsequently exposed beyond six months of age to semiannual vitamin A supplementation with high coverage as part of a national program during their preschool years," said Keith West, DrPH, MPH, George G. Graham Professor in Infant and Child Nutrition in the Bloomberg School's Department of International Health. "This benefit was limited to children whose mothers received vitamin A and not to those whose mothers received beta-carotene. Early interventions with vitamin A in communities where undernutrition is highly prevalent may have long-lasting consequences in lung health."

Vitamin A was first discovered in 1913 by E.V. McCollum, the founding chair of the School's Department of Chemical Hygiene, now Biochemistry and Molecular Biology. It was one of the first essential micronutrients to be identified. In the 1970s, Alfred Sommer, MD, MHS, dean emeritus at the Bloomberg School of Public Health, and colleagues discovered the link between vitamin A deficiency and night blindness among children in rural Indonesia and found that vitamin A given twice a year reduced childhood mortality by a third. The World Bank declared vitamin A supplementation as one of the most cost-effective medical interventions of all time.
Nutrition Horizon 13 May 2010
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Researchers Find Daily Ginger Consumption Eases Muscle Pain by 25 percent

For centuries, ginger root has been used as a folk remedy for a variety of ailments such as colds and upset stomachs. But now, researchers at the University of Georgia have found that daily ginger consumption also reduces muscle pain caused by exercise.

While ginger had been shown to exert anti-inflammatory effects in rodents, its effect on experimentally-induced human muscle pain was largely unexplored, said Patrick O'Connor, a professor in the College of Education's department of kinesiology. It was also believed that heating ginger, as occurs with cooking, might increase its pain-relieving effects.

O'Connor directed two studies examining the effects of 11 days of raw and heat-treated ginger supplementation on muscle pain. Collaborators included Chris Black, an assistant professor of kinesiology at Georgia College and State University in Milledgeville, UGA doctoral student Matt Herring and David Hurley, an associate professor of population health in UGA's College of Veterinary Medicine.

Participants in the studies, 34 and 40 volunteers, respectively, consumed capsules containing two grams of either raw or heat-treated ginger or a placebo for 11 consecutive days. On the eighth day they performed 18 extensions of the elbow flexors with a heavy weight to induce moderate muscle injury to the arm. Arm function, inflammation, pain and a biochemical involved in pain were assessed prior to and for three days after exercise.

The studies showed that daily ginger supplementation reduced the exercise-induced pain by 25 percent, and the effect was not enhanced by heat-treating the ginger.

"The economic and personal costs of pain are extremely high," said O'Connor. "Muscle pain generally is one of the most common types of pain and eccentric exercise-induced muscle pain specifically is a common type of injury related to sports and/or recreation (e.g., gardening). Anything that can truly relieve this type of pain will be greatly welcomed by the many people who are experiencing it."
Physorg.Com 19 May 2010
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Spicing the Meat Also Cuts the Cancer Risk

Spices will do more than just enhance the taste of ground beef. They may also cut down on the risk of compounds that can cause cancer.

J. Scott Smith, a Kansas State University food chemistry professor, has pursued different projects in recent years seeking ways to reduce heterocyclic amines (HCAs). HCAs are the carcinogenic compounds that are produced when muscle foods, such as ground beef patties, are barbecued, grilled, boiled or fried. Consuming HCAs through meat increases risk factors for colorectal, stomach, lung, pancreatic, mammary and prostate cancers.

Smith, in research supported by the Food Safety Consortium, found that certain spices containing natural antioxidants would reduce HCA levels by 40 percent when applied to beef patties during cooking.

"Cooked beef tends to develop more HCAs than other kinds of cooked meats such as pork and chicken," Smith said. "Cooked beef patties appear to be the cooked meat with the highest mutagenic activity and may be the most important source of HCAs in the human diet."

Previous studies have shown that meat products cooked below 352 degrees Fahrenheit for less than four minutes had low or undetectable levels of HCAs, with HCAs increasing with higher temperatures and added cooking time. It's not a good idea to lower cooking temperatures too much, so antioxidant spices with phenolic compounds can block HCAs before they form during heating and still allow high temperatures to be maintained.

Smith's research team investigated six spices -- cumin, coriander seeds, galangal, fingerroot, rosemary and tumeric -- and found that the latter three had the highest levels of antioxidant activity toward inhibiting the formation of HCAs, with rosemary as the most effective.

Consumers can take advantage of the spices by integrating them into their cooking regimen. Previous research in his laboratory has demonstrated that some commercial rosemary extracts, available for purchase on the Internet, can inhibit HCA formation by 61 to 79 percent. Smith's earlier work also showed that Thai spices can inhibit HCA formation by 40 to 43 percent.

Smith said future research in this area will investigate what some marinades or powders can do to inhibit HCAs when applied to a cooked patties. His earlier project showed that marinating steaks with certain herbs, rosemary and other antioxidant spices also reduces HCAs.
News Wise 18 May 2010
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Heart Foundation Sets the Record Straight on Antioxidants

The National Heart Foundation of Australia has released a summary of research on antioxidants which warns that drinking red wine or coffee and eating chocolate to prevent heart disease will not achieve expected results.

The Heart Foundation reviewed over 100 studies to confirm that eating fruit and vegetables and drinking tea helps lower your risk of heart disease.

To prevent or treat cardiovascular disease the Heart Foundation's clear stance is not to eat chocolate (milk or dark), drink coffee, red wine or other types of alcoholic drinks or use antioxidant supplements, such as vitamins E and C.

The Heart Foundation's detailed findings are being circulated to nutritionists, doctors and other health professionals to help them provide accurate advice to their patients. National Director of Healthy Weight at the Heart Foundation, Ms Susan Anderson said that there was no need to avoid these foods and drinks completely.

Chocolate, coffee and red wine are okay as part of a balanced diet but these findings confirm that if you re consuming them thinking you re reducing your risk of heart disease then think again, she said.

The best way to get enough antioxidants is to eat a variety of plant based foods, such as vegetables, fruit, legumes, wholegrain breads and cereals, nuts and seeds every day. Specifically, the Heart Foundation recommends;

-Eat at least two serves of fruit and five serves of vegetables every day.
-Drink black or green tea, and if you add milk, use reduced, low or no fat milk.
-Use raw cocoa powder in drinks and cooking as most commercial cocoa and chocolate will be poor sources of antioxidants.
-If you drink alcohol, drink no more than two standard drinks a day.
-If you drink coffee, drink less than five cups of paper-filtered, percolated, caféstyle or instant coffee a day.
Nutrition Horizon 18 May 2010
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Increased Cancer Risk of People with Type 2 Diabetes

Cancer and diabetes – are risk factors the same for these two diseases? Or does diabetes cause processes in the body which promote the onset or growth of cancer? It is still unclear why diabetics have a higher rate of cancer than people who are not affected by this metabolic disorder.

In order to precisely identify the types of cancer in which diabetes plays a role, Kari Hemminki of DKFZ collaborated with colleagues in Sweden and the United States to carry out the largest study ever on cancer risks of people with type 2 diabetes. The study included 125,126 Swedish citizens who had been hospitalized due to problems associated with type 2 diabetes. The epidemiologists compared the cancer incidence in these patients with that of the general population in Sweden.

The scale of the study also made it possible, for the first time, to quantify correlations between diabetes and less common types of cancer. The researchers discovered that people with type 2 diabetes have an increased risk of developing 24 of the types of cancer studied. The most significant risk elevation was established for pancreatic and liver cell cancers. The rate of these cancers in people with type 2 diabetes is elevated by factor six and 4.25 respectively compared to the general population. The epidemiologists also found the risk of cancers of the kidneys, thyroid, esophagus, small intestine and nervous system to be more than twice as high.

In addition, the study confirmed an observation suggesting that people with type 2 diabetes have a significantly lower rate of prostate cancer. This was particularly apparent in diabetes patients with a family history of the disease. The more family members are affected by diabetes, the lower is the personal prostate cancer risk. "Right now, we can only speculate about the causes," said Hemminki. "Possibly, a lower level of male sex hormones in diabetics may be among the factors that are responsible for this."

Could it be that cancer rates in study participants with type 2 diabetes appear to be increased just because their tumors happened to be found earlier as a result of hospital routine diagnostics? To rule this out, the researchers separately analyzed how many cancers had occurred in study participants after one and five years respectively following their hospital stays. Although this revealed a slightly lower risk elevation, the trend was the same.

In the industrialized countries, between two and twenty percent of the population get type 2 diabetes. Hence, this metabolic disease ranges among the greatest challenges for the public healthcare system. Type 2 diabetes, which used to be incorrectly called "old age diabetes", is characterized by insulin resistance in tissue. It means that the cells of those affected do not take up glucose from the blood upon receipt of an insulin signal.
E! Science News 21 May 2010
❁❁❁

Regular Peanut Consumption Reported to Improve Cholesterol Levels

Researchers from California and Spain combined the data from 25 nut consumption trials conducted in 7 countries among 583 men and women and concluded that regular peanut consumption improved cholesterol levels and contributed to heart health. People with higher levels of "bad" LDL cholesterol and triglycerides (blood fats) and those consuming poorer quality diets gained the most benefits from regular nut consumption, the researchers said.

Looking at the data in all the studies, the researchers found that those consuming nuts frequently - about 67g per day, about 2.4 ounces or the equivalent of two small handfuls - reduced total cholesterol by 5.1% and LDL, “bad”, cholesterol by 7.4%. Their ratio of LDL to “good” HDL cholesterol also changed by 8.3% in a favourable direction. These changes were significant ($P < .001$ for all).

Lead investigator for the study published in Archives of Internal Medicine, Dr Joan Sabaté from Loma Linda University, California, said, "Results of this study provide the best evidence yet that eating nuts reduces LDL cholesterol and improves the blood lipids profile. The findings from this analysis support those from epidemiological studies which have consistently shown that habitual nut consumption reduces the risk of heart disease. Thus, a simple change of eating nuts regularly can make a big difference in people’s health.”

Commenting on the study, Ellen Mason, a senior cardiac nurse with the British Heart Foundation, said: “Apart from salted peanuts at the pub, nuts in sugary cereals or the traditional Christmas selection, nuts have been largely lacking in our diets in the UK. What we eat is extremely important to our overall health, and adding nuts back into our diet in place of saturated fats could help to improve cholesterol levels for many people.”

FoodBev.Com 26 May 2010

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New Study Shows Infants Fed Formula with DHA and ARA Demonstrate Positive Long-Term Immune Outcomes

Results of a new study released this week in the June 2010 issue of The Journal of Pediatrics show that infants fed Enfamil LIPIL containing DHA and ARA during the first year of life experienced improved immune outcomes, including improved respiratory health, versus infants fed the same formulation without these beneficial lipids - and this health benefit was shown for the first three years of life. The study was conducted by researchers at the Retina Foundation of the Southwest.

A routine cow's milk formula supplemented with DHA and ARA (Enfamil LIPIL) or the same formula with no DHA or ARA (now discontinued Enfamil with Iron) was fed to infants within the first week of life through 12 months in randomized, double-blind studies. Results of the study revealed infants fed the supplemented formula experienced improved immune health relative to the infants fed the unsupplemented formula. In this study, immune health was assessed looking at a variety of clinical outcomes related to respiratory and skin health based on a review of infants' medical charts. Improvements were demonstrated in most of the outcomes assessed in the study.

Since the conclusion of the study, the Enfamil LIPIL formulation has been further enhanced with Natural Defense Dual Prebiotics, and is available in the marketplace under the Enfamil PREMIUM name.

Human milk is considered the gold standard in terms of nutrition for infants, since it provides a variety of biological factors, including antibodies, which help support the development of the infant's immune system. Results from this study show that mothers who cannot or choose not to breastfeed may benefit their infants' respiratory health by feeding an infant formula that has been supplemented with DHA and ARA at levels similar to the worldwide breast milk average. This new study adds to the growing body of research showing that early feeding with Enfamil formulas supplemented with expert-recommended levels of DHA and ARA supports long-term beneficial outcomes for health and development. For example, another study by Birch, et. al., published in the American Journal of Clinical Nutrition in February 2010 - titled The DIAMOND (DHA Intake and Measurement of Neural Development) Study - reported that infants fed a routine infant formula supplemented with DHA at 0.32% of total fatty acids (Enfamil LIPIL) had improved visual acuity through 12 months of age compared to infants fed the same formulation without supplementation (Enfamil with Iron). Another study of those same formulas published in Child Development by Drover, et. al., in October 2009 compared problem-solving ability among 9-month-old infants. Infants were assessed with a 2-step problem-solving task as a measure of mental development, and those who were fed the supplemented formula had more successful task completions and higher goal-directed behaviors than infants fed the unsupplemented formula.

Mead Johnson pioneered the inclusion of DHA and ARA in infant formula in the United States, and millions of babies worldwide have been fed similarly enhanced formulas. Global experts, including the World Health Organization (WHO), the

European Food Safety Authority (EFSA) and the American Dietetic Association/Dieticians of Canada, specify their use for infants who are not breastfed. As recently as March 2010, the Agence Francaise De Securite Sanitaire Des Aliments (AFSSA) recognized DHA as an essential fatty acid and set a dietary recommended intake level of 0.32% of total fatty acids by infants 6 months to 1 year of age. This is the same level found in Enfamil infant formulas. In its published opinion, AFSSA also recognized DHA as a major constituent for the brain and visual structure and function.
Medical News Today 30 May 2010
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Understanding the Relationship Between Bacteria and Obesity

Research sheds new light on the role bacteria in the digestive tract may play in obesity. The studies, which were presented at the 110th General Meeting of the American Society for Microbiology, paint a picture that may be more complex than originally thought.
"Work currently underway suggests that an interaction between genetic factors and the composition of the bacteria that inhabit the human gut may predispose certain individuals towards obesity. These results potentially provide insight into the mechanisms by which genetics may predispose some people to obesity. They could also help pave the way towards a future in which genetic screening in conjunction with individually tailored treatments could help people at risk for obesity to maintain a healthy weight," says Margaret Zupancic, of the Institute for Genome Sciences at the University of Maryland School of Medicine, who presented one of the studies.
Zupancic and her colleagues analyzed the gut bacterial communities of lean and obese individuals belonging to the Old Order Amish of Lancaster County, Pennsylvania -- a population relatively homogenous in regard to both genetics and lifestyle. Initially they found no correlation between the composition of the gut bacteria and obesity, but when they factored in the genetic makeup of the participants, certain patterns began to emerge.
One pattern was a statistically significant correlation between whether the participant carried a given variant of the FTO gene (a gene associated with obesity) and the presence of certain bacterial groups in the digestive tract.
The researchers also found that in people with certain genetic variations in taste receptor genes, a low level of bacterial diversity in the gut correlated with a higher likelihood of obesity, while a high level of diversity correlated with a lower likelihood of obesity.
"While this work is still at a relatively early stage, results such as these could lead to applications such as probiotic or antibiotic-based treatments for obesity that could be individualized based on a person's unique genetic and gut microbial makeup," says Zupancic.
Another study from the Fred Hutchinson Cancer Research Center analyzed the gut microbes of women between 40 and 45 years of age. The researchers found a positive correlation between the population of one specific type of bacteria, Bacteroidetes, and body fat percentage in the participants.
Not all research presented at the meeting found differences in bacterial populations in the gut and obesity. One study, focusing specifically on children and childhood obesity, failed to identify any significant differences in the gut microbial communities of obese and normal-weight children.
The researchers subsequently analyzed the ability of the microbes to extract and convert dietary energy. They found higher levels of short-chain fatty acids in the feces of obese children.
"This suggests that although obese and normal-weight children have similar gut microbial communities, the gut microbes in obese children are more efficient at converting dietary substrates into energy," says Amanda Payne of the Institute of Food Health and Nutrition ETH, Zurich, Switzerland.
Short-chain fatty acids are converted into triglycerides and glucose by the liver, a process estimated to provide an additional 10% of dietary energy. The increased production of short-chain fatty acids by gut microbes in obese children could potentially supply more dietary energy, resulting in weight gain.
"While the importance of a balanced diet and regular exercise should not be discounted, our results may help contribute to the development of novel approaches in treating childhood obesity by modulating the composition and activity of the gut microbiota in order to reduce energy extraction from undigested food," says Payne.
Science Daily (May 30, 2010)
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Milk: Two Glasses a Day Tones Muscles, Keeps the Fat Away in Women, Study Shows

Women who drink two large glasses of milk a day after their weight-lifting routine gained more muscle and lost more fat compared to women who drank sugar-based energy drinks, a McMaster study has found.
The study appears in the June issue of *Medicine and Science in Sport and Exercise*.
"Resistance training is not a typical choice of exercise for women," says Stu Phillips, professor in the Department of Kinesiology at McMaster University. "But the health benefits of resistance training are enormous: It boosts strength, bone, muscular and metabolic health in a way that other types of exercise cannot."

A previous study conducted by Phillips' lab showed that milk increased muscle mass and fat loss in men. This new study, says Phillips was more challenging because women not only steer clear of resistance training they also tend to steer away from dairy products based on the incorrect belief that dairy foods are fattening.

"We expected the gains in muscle mass to be greater, but the size of the fat loss surprised us," says Phillips. "We're still not sure what causes this but we're investigating that now. It could be the combination of calcium, high-quality protein, and vitamin D may be the key, and. conveniently, all of these nutrients are in milk.

Over a 12-week period, the study monitored young women who did not use resistance-training exercise. Every day, two hours before exercising, the women were required not to eat or drink anything except water. Immediately after their exercise routine, one group consumed 500ml of fat free white milk; the other group consumed a similar-looking but sugar-based energy drink. The same drinks were consumed by each group one hour after exercising.

The training consisted of three types of exercise: pushing (e.g. bench press, chest fly), pulling (e.g. seated lateral pull down, abdominal exercises without weights), and leg exercises (e.g. leg press, seated two-leg hamstring curl). Training was monitored daily one on one by personal trainers to ensure proper technique.

"The women who drank milk gained barely any weight because what they gained in lean muscle they balanced out with a loss in fat" said Phillips. "Our data show that simple things like regular weightlifting exercise and milk consumption work to substantially improve women's body composition and health." Phillips' lab is now following this study up with a large clinical weight loss trial in women.
Eurekalert (May 26, 2010)
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Artificial Sweeteners, Without the Aftertaste: Scientists Find Bitter-Blocking Ingredient

Researchers have discovered a chemical that specifically blocks people's ability to detect the bitter aftertaste that comes with artificial sweeteners such as saccharin. The key is a molecule known only as GIV3727 that specifically targets and inhibits a handful of human bitter taste receptors, according to a report published online on May 27th in *Current Biology*.

The finding of what the researchers say is the first commercially relevant small-molecule bitter taste inhibitor also opens the door to further discovery of compounds for other taste-enhancement purposes, such as hiding the yucky taste of medicines or other commonly encountered bitter flavors.

"To our knowledge, this is the first published example of a bitter receptor inhibitor with taste activity in humans," said Jay Slack of Givaudan Flavors Corp. in Cincinnati. "We applied high-throughput screening and medicinal chemistry approaches to develop specific inhibitors for human bitter taste receptors. While these methods are commonly used in the development of new drug candidates, ours is the first successful application of this technology for bitter taste modulation. This flavoring substance could be broadly used to improve the palatability of foods and beverages containing acesulfame K and saccharin."

Acesulfame K is a calorie-free sweetener sold as Sunett and Sweet One. Saccharin is often found in little pink packets at restaurants under the trade name Sweet'N Low.

In addition to its commercial potential in packaged foods and beverages, GIV3727 could also lead to important new insights in the scientific arena, the researchers said.

"Recent evidence indicates that some bitter receptors are also expressed in other nongustatory tissues with proposed roles in the detection of noxious airborne chemicals or regulation of glucose homeostasis via the gastrointestinal tract," the researchers noted in their report. "Bitter receptor antagonists hold promise as tools to explore the role of bitter receptor signaling in these other systems."

The method used by Slack, along with Wolfgang Meyerhof of the German Institute of Human Nutrition Potsdam-Rehbrücke and their interdisciplinary team, allowed the researchers to screen the activity of thousands of molecules against human bitter taste receptors, and specifically those receptors that respond to saccharin. Those studies led them to GIV3727, a chemical that was not previously known to have any particular taste properties. Further study led to the surprising discovery that GIV3727 works on five other human bitter receptors too.

Controlled human taste tests of artificially sweetened solutions with and without GIV3727 found that the ingredient had the desired effect. That is, almost everyone selected the beverages containing GIV3727 as being less bitter. Taste intensity ratings

revealed that GIV3727 had an ability to reduce bitter tastes significantly. Importantly, those effects came without interfering with study participants' ability to taste sweetness.

The researchers said that there remains some possibility that GIV3727 might work for some people a little better than it does for others, noting that even though the chemical completely abolished bitter taste receptors in the laboratory, some people were apparently still able to detect bitterness to some degree. Those differences might be explained by known differences among people in bitter taste receptor genes, the researchers said.
Physorg.Com (May 27, 2010)
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Anti-Aging Supplements May Be Best Taken Not Too Late in Life

Anti-aging supplements made up of mixtures might be better than single compounds at preventing decline in physical function, according to researchers at the University of Florida's Institute on Aging. In addition, it appears that such so-called neutraceuticals should be taken before very old age for benefits such as improvement in physical function.

The findings from rat studies, published in the journal *PLoS ONE*, have implications for how dietary supplementation can be used effectively in humans.

"I think it is important for people to focus on good nutrition, but for those of advanced age who are running out of energy and not moving much, we're trying to find a supplement mixture that can help improve their quality of life," said Christiaan Leeuwenburgh, Ph.D., senior author of the paper and chief of the biology of aging division in the UF College of Medicine.

Scientists do not fully understand all the processes that lead to loss of function as people age. But more and more research points to the mitochondrial free radical theory of aging, that as people age, oxidative damage piles up in individual cells such that the energy-generation system inside some cells stops working properly.

To address that problem, many anti-aging studies and supplements are geared toward reducing the effects of free radicals.

The UF researchers investigated the potential anti-aging benefits of a commercially available mixture marketed for relieving chronic fatigue and protecting against muscle aging. The supplement contains the antioxidant coenzyme Q10, creatine -- a compound that aids muscle performance -- and ginseng, which also has been shown to have antioxidant properties.

The study gauged the effects of the mixture on physical performance as well as on two mechanisms that underlie the aging process and many age-related disorders: dysfunction of the cells' energy producing powerhouses, known as mitochondria, and oxidative stress.

The researchers fed the supplement to middle-aged 21-month-old and late-middle-aged 29-month-old rats -- corresponding to 50- to 65-year-old and 65- to 80-year-old humans, respectively -- for six weeks, and measured how strongly their paws could grip. Grip strength in rats is analogous to physical performance in humans, and deterioration in grip strength can provide useful information about muscle weakness or loss seen in older adults.

Grip strength improved 12 percent in the middle-aged rats compared with controls, but no improvement was found in the older group.
Measurements of the function of mitochondria corresponded with the grip strength findings. Stress tests showed that mitochondrial function improved 66 percent compared with controls in middle-aged rats but not in the older ones. That suggests that supplementation might be of greater effect before major age-related functional and other declines have set in, the researchers said.

"It is possible that there is a window during which these compounds will work, and if the intervention is given after that time it won't work," said Jinze Xu, Ph.D., first author of the paper and a postdoctoral researcher at UF.

The researchers are working to identify the optimal age at which various interventions can enhance behavioral or physical performance. Very few studies have been done to show the effect of interventions on the very old.

Interestingly, although the older rats had no improvement in physical performance or mitochondrial function, they had lowered levels of oxidative damage.

That shows that reduction of oxidative stress damage is not always matched by functional changes such as improvement in muscle strength.

As a result, research must focus on compounds that promote proper functioning of the mitochondria, since mitochondrial health is essential in older animals for reducing oxidative stress, the researchers said. And clinical trials need to be performed to test the effectiveness of the supplements in humans.

"It's going to be very important to focus less on oxidative stress and biomarkers, and focus on having sufficient energy," Leeuwenburgh said. "If energy declines, then you have an increased chance for oxidative stress or failure of repair mechanisms that recognize oxidative damage -- we're seeing that the health of mitochondria is central to aging."

It is possible that although the supplement could help reduce the oxidative stress damage, because damage in much older animals was too great, energy could not be restored.

The different compounds in the mixture acted to produce effects that single compounds did not, because each component affected a different biochemical pathway in the body, addressing both oxidative stress and mitochondrial function, researchers said.

"People are catching on that using a single compound is not a good strategy -- you have to use multiple compounds and target one or multiple pathways," Leeuwenburgh said.

The manufacturers of the supplement donated the quantity used in the study and provided support for the postdoctoral researcher and analyses. The animals used in the study were paid for through grants from the National Institute on Aging.
ScienceDaily (May 25, 2010)

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New Associations between Diabetes, Environmental Factors Found by Novel Analytic Technique

Got diabetes? If so, you probably know that the adult-onset form of the disease can be triggered by, among other things, obesity and a fatty diet. You're also more likely to develop diabetes if other family members have it. But a new study by researchers at the Stanford University School of Medicine suggests that you should also begin looking suspiciously at other aspects of your life -- like your past exposure to certain pesticides or chemicals and even one form of vitamin E.

In fact, the association of some of these so-called "environmental" cues with diabetes surpasses that of the best genetic markers scientists have identified for the disease.

Identifying relationships between a person's environment (such as tobacco exposure) and specific health repercussions (such as cancer) is nothing new. Epidemiological studies of large groups of people have been doing just that for decades. But they are limited in their ability to assess the hundreds or even thousands of variables that comprise the intricate fabric of our everyday lives. (What's your risk of heart disease if you smoke sparingly and eat fatty foods, but are also a marathoner?) They're also not open-ended: The researcher has to begin with presuppositions about possible relationships. (Does folic acid prevent birth defects?)

In this new study, the scientists relied instead on an unconventional approach that treats environmental variables as "genes." That conceptual shift allowed them to use some of the same techniques initially developed to identify the many sections of DNA throughout the genome that might contribute to disease development. Bioinformatics expert Atul Butte, MD, PhD, assistant professor of pediatric cancer biology, compared the data generated by the new approach to the amount and types of information gleaned from a DNA microarray.

"This approach catapults us from being forced to ask very simple, directed questions about environment and disease into a new realm in which we can look at many, many variables simultaneously and without bias," said Butte, who is also director of the Center for Pediatric Bioinformatics at Lucile Packard Children's Hospital. "In the future, we'll be able to analyze the effect of genes and environment together, to find, perhaps, that a specific gene increases the risk of a disease only if the person is also drinking polluted well water."

Specifically, in this study, Butte and his coworkers used the technique to identify a previously known association between people with type-2 diabetes and a class of organic compounds called polychlorinated biphenyls, or PCBs, commonly used for many applications until the late 1970s. They also uncovered a strong, but unexpected, relationship between diabetes and high levels of a form of vitamin E called gamma-tocopherol, which is prevalent in fruits, vegetables, nuts and milk.

The scientists are careful to caution, however, that an association doesn't necessarily mean that vitamin E or pollutants cause type-2 diabetes, and that more research is needed to fully understand these complex relationships.

Butte is a senior author of the research, which will be published May 20 in the online journal *PLoS ONE*. The genetic studies on which the research is based are called "genome wide association studies" or GWAS. In a nod to its origin, the scientists coined the term "environment wide association studies," or EWAS, for the new technique. They expect that EWAS will be useful in the analysis of many complex diseases.

"We've known for decades that environmental factors play a major role in diseases like diabetes, cancer and heart disease," said Jeremy Berg, PhD, director of the National Institute of General Medical Sciences, which partially supported the work. "By enabling us to measure the impact of these factors, this new approach will shed light on how genes and the environment influence our health and could provide insights into new ways to control some of our nation's most serious health problems."

Graduate student Chirag Patel conceived of, designed and executed the computer software for the EWAS. He, Butte and associate professor of medicine Jayanta Bhattacharya, MD, PhD, used existing population studies conducted from 1999 to 2006 by the U.S. Centers for Disease Control and Prevention as part of the National Health and Nutrition Examination Survey. The researchers realized that the databases contained a goldmine of information, including the levels of pollutants and vitamins in subjects' blood and urine as well as clinical measurements such as fasting blood sugar levels.

In all, the scientists analyzed the relationship of 266 unique environmental variables to the likelihood that a person's fasting blood sugar level was 126 milligrams or higher per deciliter (between 70 and 110 mg/dL is considered normal). Higher-than-normal blood sugar levels after an overnight fast are a telltale sign of diabetes. They adjusted for the subjects' age, gender, body mass index, socioeconomic status and ethnicity. Finally, they grouped related variables into 21 classes -- such as dioxins, polychlorinated biphenyls, phthalates, etc. -- similar to how individual genes are assigned to chromosomal units in GWAS.

Butte and his colleagues found that people with relatively higher levels of the pesticide-derivative heptachlor epoxide (a chemical whose use stopped in the '80s but is still prevalent in food, soil and water) in their blood were more likely than those with lower levels to also have high fasting blood sugar levels (odds ratio = 1.7). The same was true for those with high levels of PCBs (OR = 2.2) and the gamma-tocopherol form of vitamin E (OR = 1.5). In contrast, high beta-carotene levels were slightly protective (OR = 0.6).

Scientists have recently made large strides in measuring genetic associations to complex disease, but are still far from using genes to predict risk for complex chronic diseases or even plan preventive measures. On the other hand, our environmental profile is potentially more modifiable and also may provide a more complete model of disease risk when combined with genetic information.

"Studying relationships between a person's environment and their disease burden in this manner is going to be far more impactful," said Butte. "We can now imagine what it might be to look at everything in the environment, in the same way that we've been doing with the genome for the past decade. Imagine one day wearing a chip on your clothing that assesses your exposure to hundreds or thousands of environmental toxins. You could bring that in to your annual physical and you and your doctor could incorporate the information into discussions about disease risk and prevention."

The researchers are planning to conduct similar EWAS studies focused on other diseases, including cancers. They'll also try to reproduce the data from the National Health and Nutrition Examination Survey studies on specific populations in California.

In addition to NIGMS, the research was funded by the National Library of Medicine, the National Institute on Aging, the Lucile Packard Foundation for Children's Health and the Howard Hughes Medical Institute.
ScienceDaily (May 21, 2010)
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Faster Salmonella Detection Now Possible With New Technique

Using technology available through a local company, an Iowa State University researcher is working on a faster method to detect and genetically identify salmonella from contaminated foods.

Byron Brehm-Stecher, an assistant professor of food science and human nutrition, wants to replace the current system of salmonella detection with a new approach that can provide DNA sequencing-like results in hours rather than days. Brehm-Stecher's collaborator, Advanced Analytical Technologies, Inc., from Ames, is providing advanced biomedical instruments and reagents for the research.

The recent results of the research, funded by the Grow Iowa Values Fund, will be presented at the August meeting of the International Association for Food Protection in Anaheim, Calif.

Currently, definitive genetic identification of food-borne pathogens is done using traditional DNA sequencing methods first developed in the 1980s.

"If you want (DNA) sequence information now, you first need to run a polymerase chain reaction (PCR) on total DNA extracted from a sample of contaminated food," said Brehm-Stecher. "This amplifies DNA from the pathogen you're looking for and will let you know if salmonella is present or not.

"However, further details about the pathogen are lacking, like what strain is present. To dig deeper, you need to run a cycle sequencing reaction -- similar to a long PCR reaction -- and send the output from this to a DNA sequencing core facility. Results are available about two days later," said Brehm-Stecher.

"This is not fast enough to keep up with the pace of today's food production and distribution networks. We are able to get foods from the farm to the table -- really any table around the globe -- in a remarkably short period of time," he added.

Faster detection of specific strains can mean recognizing an outbreak sooner and stopping tainted food from being delivered and consumed. The new method might be helpful for investigative agencies, Brehm-Stecher said.

"Especially for the type of investigation where things are still in motion. The food has been shipped and you may not know where it is. It may be in a truck, on a shelf or in some consumer's pantry, so time really is of the essence," he said.

"Next-generation sequencing tools are available, but these are still too complex and expensive for routine use in the food industry," Brehm-Stecher explained. "New approaches that are able to bridge the gap between the limitations of traditional PCR and next-generation sequencing could enhance food safety efforts by providing both rapid presence/absence testing and detailed genetic characterization of isolates."

You don't have to go further than the local newspaper to see the depth of the problem. Recent national outbreaks of salmonella in foods include peanut butter (2007 and 2009), alfalfa sprouts (2009), black pepper and hydrolyzed vegetable protein (HVP) (2010). Adding to the problem is the fact that peanut butter, black pepper and HVP are all base ingredients used in many other food products. Salmonella in these ingredients has led to thousands of product recalls, hundreds of illnesses and several deaths, Brehm-Stecher said.

The method being developed at Iowa State University starts with a rapid PCR reaction that amplifies a salmonella-specific gene, generating millions of fluorescently labeled copies of this DNA in about 20 minutes.

Next, instead of cycle sequencing, the PCR product is purified for five minutes, SNAP71 (a reagent developed by Advanced Analytical) is added, and the DNA is heated for 10 minutes at 100ºC.

This reaction chemically cuts the labeled salmonella DNA at all adenine and guanine sites (A's and G's) in the DNA chain.

The result is a complex soup of fluorescently labeled DNA fragments of all sizes. These fragments are then separated in a high-voltage electric field by sieving them through a polymer matrix (a gel) contained in glass capillaries that are 50 microns -- not much thicker than a human hair. This process separates the DNA fragments according to their size, from smallest to largest, and each piece is detected as it passes in front of an intense light source. For a PCR product that's 300 bases long, this separation and detection process takes approximately 90 minutes.

Because the SNAP71 reagent cleaves the salmonella DNA only at adenine and guanine, and not at thymine and cytosine sites (T's and C's), the method is not a direct replacement for DNA sequencing. Instead, the process rapidly generates a reproducible pattern of DNA fragments, Brehm-Stecher said.

Salmonella strains having slightly different DNA sequences within a given gene will yield different patterns of fragments, allowing discrimination of different strains of salmonella.
From "food to finish," the whole process can be accomplished in about two and a half hours.
"We're very excited about this approach and about the rapid progress we've made since the project began," said Brehm-Stecher. "The funding for this project has enabled us to work very closely with Advanced Analytical and accelerate application of their instruments to solving important food safety problems."

The team at Iowa State University includes post doctoral researcher Hyun Jung Kim and master's student Brittany Porter. The group is also working with Cleveland Clinic in Ohio.

The ultimate goal of the project is faster detection and characterization of human pathogens from "farm to fork to physician."

Advanced Analytical's instruments are based on technology originally developed at Iowa State University in the lab of Ed Yeung, the Robert Allen Wright Professor and Distinguished Professor in Liberal Arts and Sciences and professor at the U.S. Department of Energy's Ames Lab.
Innovations Report 5 May 2010
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Why Is Breast Milk Best? It's All in the Genes

Is breast milk so different from infant formula? The ability to track which genes are operating in an infant's intestine has allowed University of Illinois scientists to compare the early development of breast-fed and formula-fed babies. They say the difference is very real.
"For the first time, we can see that breast milk induces genetic pathways that are quite different from those in formula-fed infants. Although formula makers have tried to develop a product that's as much like breast milk as possible, hundreds of genes were expressed differently in the breast-fed and formula-fed groups," said Sharon Donovan, a U of I professor of nutrition.
Although both breast-fed and formula-fed babies gain weight and seem to develop similarly, scientists have known for a long time that breast milk contains immune-protective components that make a breastfed-infant's risk lower for all kinds of illnesses, she said.

"The intestinal tract of the newborn undergoes marked changes in response to feeding. And the response to human milk exceeds that of formula, suggesting that the bioactive components in breast milk are important in this response," she noted.
"What we haven't known is how breast milk protects the infant and particularly how it regulates the development of the intestine," she said.

Understanding those differences should help formula makers develop a product that is more like the real thing, she said. The scientists hope to develop a signature gene or group of genes to use as a biomarker for breast-fed infants.
Many of the differences found by the scientists were in fundamental genes that regulate the development of the intestine and provide immune defense for the infant.

In this small proof-of-concept study, Donovan used a new technique patented by Texas A&M colleague Robert Chapkin to examine intestinal gene expression in 22 healthy infants -- 12 breast-fed, 10 formula-fed.
The technique involved isolating intestinal cells shed in the infants' stools, then comparing the expression of different genes between the two groups. Mothers in the study collected fecal samples from their babies at one, two, and three months of age.
Scientists were then able to isolate high-quality genetic material, focusing on the RNA to get a gene expression or signature.
Donovan said that intestinal cells turn over completely every three days as billions of cells are made, perform their function, and are exfoliated. Examining the shed cells is a noninvasive way to examine intestinal health and see how nutrition affects intestinal development in infants.

Understanding early intestinal development is important for many reasons, she said.
"An infant's gut has to adapt very quickly. A new baby is coming out of a sterile environment, having received all its nutrients intravenously through the placenta. At that point, babies obviously must begin eating, either mother's milk or formula.
"They also start to become colonized with bacteria, so it's very important that the gut learns what's good and what's bad. The baby's body needs to be able to recognize a bad bacteria or a bad virus and fight it, but it also needs to recognize that even though a food protein is foreign, that protein is okay and the body doesn't want to develop an immune response to it," she said.
If anything goes wrong at this stage, babies can develop food allergies, inflammatory bowel disease, and even asthma. "We're very interested in frequent sampling at this early period of development," she added.

Donovan also would like to learn how bacteria in the gut differ in formula- and breast-fed babies, and this technique should make that possible. "Now we'll be able to get a complete picture of what's happening in an infant -- from the composition of the diet to the microbes in the gut and the genes that are activated along the way."
Of potential clinical importance: The gene expressed most often in breast-fed infants is involved in the cell's response to oxygen deprivation. Lack of oxygen is a factor in the development of necrotizing enterocolitis (NEC), a kind of gangrene of the intestine that can be fatal in premature babies. NEC is a leading cause of disease and death in neonatal intensive care units, with a reported 2,500 cases occurring annually in the United States and a mortality rate of 26 percent.
Eurekalert (May 12, 2010)
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Maintaining Energy Balance during Races May Protect Cyclists' Bones, Researcher Says

The recent start of the North American cycling season marks the beginning of a physically demanding time for elite and professional bicycle racers who participate in multi-day stage races. Previous research has found that competitive cyclists have significantly lower bone mineral density (BMD) than other endurance athletes, making them more susceptible to fractures. The reasons for the reduced bone mass in elite cyclists are not fully understood, but one explanation is an imbalance between bone formation and bone breakdown due to the high-energy cost of stage racing.

However, a new University of Missouri study reveals that proper nutrition during multi-day stage races might prevent harmful changes in bone turnover.

MU researchers found that athletes who maintained energy balance by matching their energy intake to their energy expenditure showed increased markers of bone turnover -- the process of breaking down old bone and forming new bone. Because the increase in bone formation was greater than the increase in bone breakdown, the researchers concluded that these changes were not likely to negatively affect bone mass in the long-term.

"The findings suggest that participation in stage races might not have negative effects on bone turnover if energy intake matches the energy cost of high-intensity racing over several days," said Pam Hinton, associate professor in the Department of Nutrition and Exercise Physiology. "The results are consistent with the practical recommendation that elite cyclists should match their energy intake to the high energy demands of stage racing."

In the study, Hinton examined markers of bone formation and bone breakdown in the blood of elite cyclists who participated in the Tour of Southland, a six-day, 10-stage cycling race. Hinton found significant increases in markers of bone formation and bone breakdown among the athletes whose energy intake matched their energy expenditure throughout the race.
Disrupted bone turnover, that is, reduced bone formation and increased bone breakdown, due to inadequate energy intake relative to expenditure is just one possible cause of low BMD among cyclists. Other factors include low-body weight, increased loss of calcium through sweat and significant time spent cycling, which exerts only minimal mechanical loading on the skeleton.

"This study measured only the short-term effects of stage racing on bone turnover; future studies should assess the long-term effects," Hinton said.
The study, "Bone formation is increased to a greater extent than bone resorption during a cycling stage race," will be published in *Applied Physiology Nutrition and Metabolism*. This is the first study to examine bone turnover during a cycling stage race.
E! Science News (May 5, 2010)
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Rye and Barley Products Facilitate Blood Glucose and Appetite Regulation

Evidence from observational studies indicates that diets rich in whole grain reduce risk of obesity and other diseases related to the metabolic syndrome e.g. type 2 diabetes and cardio-vascular disease. The mechanisms involved are only partially elucidated. Work within HEALTHGRAIN has revealed novel insights regarding some potential mechanisms.

Barley products rich in indigestible carbohydrates (dietary fibre and resistant starch), facilitated glycaemic regulation through a mechanism involving fermentation by gut micro-organisms. Fermentation was associated with release of specific gut hormones (GLP-1), with acknowledged benefits on a variety of parameters associated with reduced risk of the metabolic syndrome, including benefits on perceived satiety.

GLP-1 is currently investigated for use as an antidiabetic, antiobesity drug, but appears to be produced endogenously in healthy subjects after intake of certain whole grain barley products rich in indigestible carbohydrates. Addition of whole grain barley products with slow glycemic response and rich in dietary fibre and resistant starch in test meals significantly improved insulin sensitivity in type 2 diabetic subjects as compared with whole grain wheat or white wheat.

Additionally, rye products generally produce a beneficial blood glucose profile following a meal, with a low and sustained blood glucose response. Rye products also induced lowered insulin response compared with white wheat, promoted higher post-meal satiety, and induced lowered voluntary energy intake at a subsequent meal. Studies within HEALTHGRAIN indicate that different rye genotypes vary with respect to benefits on glycaemic regulation and insulin demand.

The results are in favour of metabolic benefits of an increased consumption of in particular whole grain barley products with low glycemic response, and foods made of certain rye varieties. The results provide tools for tailoring of whole grain cereal products with magnified health benefits adjunct to the metabolic syndrome.

ScienceDaily (May 5, 2010)
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Researchers Recommend Pregnant Women Take 4,000 IU Vitamin D a Day

Taking vitamin D supplements during pregnancy is not only safe for mother and baby, but also can prevent preterm labor/births and infections, according to results of a randomized controlled study to be presented at the Pediatric Academic Societies (PAS) annual meeting in Vancouver, British Columbia, Canada.

In the 1950s and '60s, people were concerned that vitamin D could cause birth defects, according to Carol L. Wagner, MD, lead author of the study and a pediatric researcher at Medical University of South Carolina. It now is known that vitamin D is important for maternal and infant health, including bone health and immune function.
Recent studies have shown that vitamin D deficiency during pregnancy is a serious public health issue.

"Diet doesn't provide enough vitamin D, and we don't go in the sun as much as we need," Dr. Wagner said.
Therefore, she and her colleagues, including Bruce W. Hollis, PhD, who has worked in the field of vitamin D research for the last 30 years, set out to determine the optimal dose of vitamin D supplements for pregnant women without doing harm.

Researchers randomized 494 pregnant women at 12-16 weeks' gestation into three treatment groups. Group one received 400 International Units (IU) of vitamin D a day until delivery; group two received 2,000 IU and group three received 4,000 IU. The women were evaluated monthly to ensure safety.

"No adverse events related to vitamin D dosing were found in any of the three arms of the study," Dr. Wagner said.
Investigators also looked at the effects of vitamin D supplementation on complications during pregnancy, including preeclampsia, gestational diabetes, infections, and preterm labor and birth.

"The spectacular part of the study was it showed women replete in vitamin D had lower rates of preterm labor and preterm birth, and lower rates of infection," Dr. Wagner said.
The greatest effects were seen among women taking 4,000 IU of vitamin D per day. Therefore, the researchers recommend this daily regimen for all pregnant women.

AAP News Room (May 1, 2010)
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Reducing Salt Intake Benefits Kidney Patients

Lowering salt intake may help reduce fluid build-up in kidney patients and be more effective in reducing high blood pressure than antihypertensive medications, according to an analysis appeasing online May 27 in the Clinical Journal of the American Society Nephrology (CJASN).

Dry-weight is a kidney disease patient’s weight immediately after dialysis, when he or she does not carry the excess fluid that builds up between dialysis treatments. Dry-weight is the lowest weight one can safely reach after dialysis without developing symptoms of low blood pressure such as cramping, which can occur when too much fluid is removed. If a patient lets too much fluid buildup between sessions, it is harder to get down to a proper dry-weight.
Achieving and maintaining dry-weight can improve blood pressure between dialysis sessions and limit hospitalizations. This appears to be an effective but forgotten strategy in controlling and maintaining blood pressure control among hypertensive patients on dialysis.

Researchers found that dry-weight can be assessed inexpensively through relative plasma volume monitoring (which uses photo-optical technology to assess changes in volume of a patient’s blood) and body impedance analysis (which determines lean body mass).They also discovered that restricting salt intake can help control blood pressure and make it easier for patients to get down to a proper dry-weight.

Studies suggest that salt restriction and dry-weight reduction through dialysis together provide more benefits to the heart than antihypertensive medications. This could have important clinical implications because most patients with chronic kidney disease die from cardiovascular causes.
Food Product Design 05/31/2010
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Omega-3's Linked to Healthier, Stronger Bones

Increased intake of omega-3 fats, and DHA (docosahexaenoic acid) in particular, increases bone mineral content and produces healthier, stronger bones -- at least according to the results of a study with rats. The findings did not extend to EPA (eicosapentaenoic acid), however. Researchers used dual-energy X-ray absorptiometry to assess bone mineral content in the rats.

However, the omega-3 fat EPA also has its proponents in this regard, according to NutraIngredients: *"Scientists from NASA recently reported in the Journal of Bone and Mineral Research that the omega-3 EPA may protect against bone loss during space flight, a result that challenges the [rat study] data."*

Mercola.com May 29 2010

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Health & Nutrition News

Probiotic Invention Helps Prevent Lactose Intolerance Symptoms

Ganeden Biotech announced that it was granted a patent by the United States Patent and Trademark Office for its invention utilizing a combination of probiotics and lactase to increase lactose digestion in people with lactose intolerance. Lactose intolerance, or the inability to digest lactose, impacts up to 50 million Americans, plaguing sufferers with diarrhea, gas, and/or bloating after they consume foods containing dairy. The new invention promises a better and easier solution to prevent lactose intolerance symptoms over the traditional practice of taking lactase enzyme alone before a meal, which lactose intolerance sufferers often find impractical.

According to the National Institutes of Health, up to 50 million Americans show signs of lactose intolerance. Lactose intolerance occurs across all ethnic populations, but members of certain ethnic groups are hit particularly hard, with some 90 percent of Asians and 80 percent of blacks and Hispanics reporting lactose intolerance symptoms. Symptoms can range from mild discomfort to severe nausea. Gas and diarrhea can begin within 30 minutes and last for hours after eating or drinking food containing lactose, the main sugar found in milk. The gastrointestinal (GI) distress occurs when undigested lactose, the natural sugar found in milk, irritates the upper digestive tract and ferments in the lower digestive tract.

Taking lactase, the enzyme that breaks down lactose and what people with lactose intolerance lack, is the traditional solution for people with lactose intolerance who want to consume dairy and is a seemingly simple solution. However, people with lactose intolerance often find this solution burdensome, as the lactase enzyme must be taken every time dairy is consumed because it can only work when lactose is in the upper digestive tract. Additionally, many of today's non-dairy foods such as breads, cereals, salad dressings, and snacks, contain dairy products, which are included as ingredients or processing aids to boost protein content or improve texture, leading to what experts call "hidden dairy."

"Keeping enough lactase pills handy is hard enough, but since lactose intolerance sufferers often don't know that some of the foods they're eating contain dairy, they may not even think about taking their lactase pills," said Dr. Rachel Garber, a Cleveland pediatrician who treats lactose intolerant children and teens at her practice. "A better solution would be one that could be taken in the morning and protect you throughout the day against any dairy that might be consumed, knowingly or not."

Ganeden Biotech, a Cleveland-based biotechnology company has been successfully selling a product at retail stores under its Digestive Advantage brand, called Digestive Advantage Lactose Intolerance. It contains the combination of a probiotic strain of Bacillus coagulans and lactase enzyme covered by patent # 7,700,093, which was just issued by the United States Patent and Trademark Office. Studies conducted by the Dutch research firm TNO demonstrated that the combination was able to increase lactose digestion throughout the digestive tract. This was an important finding since orally consumed lactase enzyme can only work to break down lactose in the upper digestive tract and is not effective for lactose that makes it to the lower digestive tract.

"The lactase enzyme market is rather stagnant, with the leading brands declining in sales. We believe this is because it's not the ideal solution to lactose intolerance -- it's not always easy to take a lactase pill before eating dairy, especially if you don't know that the food you're about to eat contains dairy," said Marshall Fong, who heads the marketing team at Ganeden. "Our Digestive Advantage Lactose Intolerance combines lactase enzyme plus probiotics to increase lactose digestion throughout the digestive tract. People love our product because it works, and because they don't need to take it with every meal."

Nutrition Horizon 12 May 2010

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NZ Sleep Enhancing Milk Popular in Taiwan

Taiwanese trials of a New Zealand sleep enhancing milk product proved there was interest. But joint venture partners New Image Group and Somnaceutics have been stunned by the demand for the milk powder-based drink since it launched six weeks ago.

Stephen Lyttelton, chief executive of health and wellness product group New Image, says the first shipment of Sleep Time sold out to its 20,000 Taiwanese distributors within half an hour of the product’s launch.

He says the demand confirms clinical trials in Taiwan that saw 88% of users report significant sleep improvement. People in the trials kept sleep diaries and gauged the product's effectiveness.

Production in New Zealand is now being ramped up and Somnaceutics is adding more cows to the special dairy herds that produce milk containing a high level of sleep enhancing peptides.

The Auckland-based bio-technology company was established in 2007 to commercialise the discovery that certain cows carried peptides believed responsible for the sleep-enhancing effect of their milk. The peptides were discovered by Somnaceutics' founding scientist and director Professor Bob Elliott. Prof Elliott, who is also the founding scientist of Living Cell Technologies, also developed the proprietary manufacturing process to stabilize the milk, extending the life of certain milk fractions in the body's circulation.

Another Somnaceutics shareholder is its board chairman Gary Pace, a former Fullbright Fellow at the Massachusetts Institute of Technology. Dr Pace is also a director of ResMed which develops, manufacturers and markets products for the screening, treatment and management of sleep and respiratory disorders.

The joint venture in Taiwan came about after New Image's research among its more than 5000 direct selling distributors in Taiwan had shown it that sleep deprivation is a real concern to Taiwanese living a high-pressure lifestyle. A study by the Taiwan Society of Sleep Medicine also showed that the number of Taiwanese suffering from lack of sleep has doubled in three years to 22% of the country's population of 23 million now having chronic insomnia and up to 60% suffering some form of sleep deprivation.

New Image sought the exclusive right to distribute the Somnaceutics milk powder through its direct selling channels in Taiwan and the joint venture partnership was established late last year.

Guy Wills, Somnaceutics' chief executive, says the flavoured milk powder, which is mixed with a small amount of water, has a natural soporific effect and has been shown in clinical trials to provide a statistically significant improvement in quality of sleep and most notably on increasing time spent in the important rapid eye movement (REM) sleep phase.

"Taiwanese like the fact that it is a natural product that has been scientifically developed and is clinically proven," Mr Wills says. "The product was pretested with Taiwanese consumers and this helped fine tune elements such as flavour, formulation and packaging. The Taiwanese also like that it not only helps with sleeping, but also has strong nutritional benefits. It has less than 1% fat and is lactose free. Magnesium has been added to help muscles relax and for utilisation of calcium."

Somnaceutics won the Cawthron Institute award for Innovation in Science and Technology for Sleep Time in the Natural Products New Zealand Industry Awards last month.

Scoop 28 May 2010

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What's More Important in the Obesity Battle – Physical Activity or Medical Treatment?

Experts disagree in the *British Medical Journal* about the best way to tackle the obesity crisis. While Professor Louise Baur and colleagues from the Children's Hospital at Westmead and the University of Sydney in Australia acknowledge that "physical inactivity is a major contributor to the global burden of disease," they says that it would be wrong to only focus on this and ignore the problem of obesity.

Baur and colleagues argue that physical inactivity is just one marker and that there is substantial evidence that unhealthy diets low in fibre and high in sugar and large portion size are also responsible for obesity and the diseases associated with it.

However, Dr Richard Weiler, a specialist registrar in sport and exercise medicine at Imperial College Healthcare NHS Trust and general practitioner, and colleagues believe that inadequate cardio-respiratory fitness causes disease more than excess body fat, waist size and body mass index.

Weiler and colleagues maintain that "physical inactivity is one of the greatest health threats facing developed nations today" and they are concerned that 95% of the populations in England and the United States do not meet the recommended guidelines of doing 30 minutes moderate to vigorous physical activity on at least five days a week or equivalent.

They say this is alarming given that physical inactivity rather than obesity per se is an actual cause for many illnesses including obesity, heart disease, type 2 diabetes, mental health problems, high blood pressure and dementia.

Spending huge amounts on treating obesity is not the right way forward, they argue. Weight loss drugs and surgery are risky and the long-term benefits are limited and they certainly do not have the associated health benefits linked to physical activity. They conclude that it is time for health policy and healthcare professionals to focus on fighting physical inactivity, a "chronic disease that has an adult population prevalence of 95%."

Professor Baur, on the other hand, believes that "on its own, improving physical activity will have little impact on reducing overall levels of already established obesity."

She believes that obese people need access to high quality treatment provided by well-trained professionals to deal with their weight and any linked health problems.

In conclusion, Professor Baur and colleagues advocate tackling obesity with a range of strategies, for example, increasing physical activity, improving diet and lifestyles. They say urban planning should be developed to encourage people to use their car less and cycle more and public transport should be made more accessible and affordable.

ScienceDaily (May 26, 2010)

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New Vitamin D Recommendations for Older Men and Women

The International Osteoporosis Foundation (IOF) has released a new position statement on Vitamin D for older adults, which makes important recommendations for vitamin D nutrition from an evidence-based perspective. Vitamin D is important for bone and muscle development, function and preservation. For this reason it is a vital component in the maintenance of bone strength and in the prevention of falls and osteoporotic fractures.

The objective of this statement, published in the leading bone journal, *Osteoporosis International (OI DOI 10 1007/s00198-010-1285-3),* was to use and examine all available evidence to support new recommendations for optimal vitamin D status. The best available clinical indicator of vitamin D status is serum 25OHD and vitamin D intake and effective sun exposure are the major determinants of this level. Serum 25OHD levels decline with ageing but the response to vitamin D3 supplementation is not affected by age or by usual calcium dietary intake.

Preventing vitamin D deficiency has a major impact on falls and osteoporotic fractures. Vitamin D deficiency is associated with decreased muscle strength in older men and women and supplementation improves lower limb strength and reduces risk of falling. Vitamin D affects fracture risk through its effect on bone metabolism and on falls risk.

Key recommendations:

- The estimated average vitamin D requirement of older adults to reach a serum 25OHD level of 75 nmol/l (30ng/ml) is 20 to 25 µg/day (800 to 1000 IU/day).
- Intakes may need to increase to as much as 50 µg(2000IU) per day in individuals who are obese, have osteoporosis, limited sun exposure (e.g. housebound or institutionalised), or have malabsorption.
- For high risk individuals it is recommended to measure serum 25OHD levels and treat if deficient.

The lead author of the statement, Professor Bess Dawson-Hughes of Tufts University, US, stated that, "Global vitamin D status shows widespread insufficiency and deficiency. This high prevalence of suboptimal levels raises the possibility that many falls and fractures can be prevented with vitamin D supplementation. This is a relatively easy public health measure that could have significant positive effects on the incidence of osteoporotic fractures."

Machines Like Us (May 10, 2010)

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Rural to Urban Migration Associated With Increased Obesity and Diabetes Risk in India

Migration from rural to urban areas is associated with increasing levels of obesity and is a factor driving the diabetes epidemic in India, according to a new study published in *PLoS Medicine*.

India, like the rest of the world, is experiencing a diabetes epidemic. Diabetes has increased in urban areas of India from 5% to 15% between 1984 and 2004. As in other developing countries this is thought to result from increased consumption of saturated fats and sugar and reduced levels of physical activity. The process of urbanization -- migration from rural areas to towns and cities and the expansion of urban areas into the periphery -- is linked to changes in diet and behaviour. To examine how migration has impacted on obesity and diabetes in India, Shah Ebrahim and colleagues interviewed rural migrants working in urban factories.

The researchers recruited rural-urban migrants working in four factories in central, north and south India and the spouses of these workers if they were living in the same town. Each migrant worker or spouse asked a sibling still living in the rural area that they were originally from to join the study. Non-migrant factory workers and their siblings from urban areas were also recruited. Each participant answered questions about their diet and physical activity and had their blood sugar and body mass index measured.

The results showed similar levels of obesity in urban and migrant men (41.9% and 37.8% respectively), in comparison with 19% of men in rural areas. Diabetes also stood at similar levels in urban and migrant men (13.5% in urban and 14.3% respectively), in comparison with 6.2% in rural men. These patterns of obesity and diabetes were similar in women.

The findings demonstrate that rural-urban migration in India is associated with rapid increases in obesity and diabetes and also indicated that changes in migrant behaviour -- such as reduced physical activity -- put them at similar risk to the urban population. The authors conclude that health promotional activities targeting migrants and their families would help reduce the risk factors for obesity and diabetes and slow the progress of the epidemic.

E! Science News (April 27, 2010)

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Potential market for ready to eat food as Indian consumers explore options redefining taste, health and convenience equation

Does the idea of cooking an elaborate meal after a long working day bother you? Do you fancy experimenting with delicacies native to various parts of India at home? Do you wish to match up to your mother-in-laws legendary culinary skills? Does the idea of having unexpected guests give you living nightmares? If yes, then a Ready-To-Eat (RTE) food pack might just be what you are looking for.

Though steaming hot Mutter Paneer and Dal Tadka continue to grace Indian tables, many today choose to take the easier course. For a generation of Indians who are increasingly pressed for time, the growing availability of a variety of RTE foods across India is being considered a viable option.

Emerging Opportunities in the Indian Ready-to-Eat Foods Market - a recent consumer insight report published by Datamonitor, predicts that the RTE foods market in India which was mainly driven by the export demand until recently, has matured to a stage where there is a tremendous potential for growth over the next few years.

In 2009, Indian RTE foods market was estimated to be around $33.5m, registering a CAGR of approximately 15% over the last five years. At present, RTE foods with normal shelving, i.e., canned RTE foods that require no refrigeration, alone contribute to approximately 60% of the total market. “For a product, which predominantly depended on the export markets to strike a chord with both the rising popularity of Indian cuisines and the burgeoning Indian diaspora across the globe, the recent rise in demand in the local market is substantial one”, commented Pinaki Mukherjee, Lead Consultant with Datamonitor India’s Consumer Markets team.

The role of women in an urban Indian family has undergone a massive transformation. Women today, have very little time to involve in regular household chores like cooking. This factor is predominantly driving the growth of convenience foods such as

RTE in India. “With the increasing involvement of women in India’s labor force, rising number of nuclear families and a desire to maximize “me” time, the Indian RTE foods market size is poised to double by 2014,” said Pinaki.

Lifestyle changes have necessitated modifications in most urban Indians’ diet regime in terms of meal time fragmentation and diet diversification. With these changes, it has increasingly become a challenge for Indians to maintain a diet that is balanced and convenient, yet caters to the Indian taste buds. The desire to eat fresh food among Indians is currently so prominent that it even overshadows the desire for consumers to seek variety and authenticity. This was corroborated by the findings of the recent Datamonitor consumer survey, where consumers across all the age groups said that they value ‘Freshness’ claims more than authenticy and originality. While most RTE manufacturers promote quality claims on packaging, no one has made attempts to break the unhealthy perception of packaged food by highlighting that the retort packaging used in RTE foods can help in retaining the nutritive value and freshness of the product. There is a need for Manufacturers to focus on making assurance of freshness as a key component of their marketing efforts to increase the uptake of RTE foods.

Health concerns on part of the consumers also pose difficulty to the RTE manufacturers. With a larger number of Indians making a conscious attempt to eat healthy, they are on a look out for health claims like low cholesterol and trans-fat free tagged to the product.,. The Datamonitor consumer survey lent credence to this phenomenon, wherein it was found that ‘low or lowers cholesterol’ and ‘low or reduced fat’ has a high level of influence on 50% of the Indians’ choice of food and beverages. Since most RTE foods in India have a considerably high amount of fat in their formulations, manufacturers have to address this issue by aligning their offerings to appeal not only to the consumers’ palette, but also to their desire to eat healthy.

In the process of tapping the RTE food market, manufacturers need to identify potential opportunities in terms of novel product concepts and packaging formats. Given the diversity of regional cuisines and the increasing nature of Indians to experiment with respect to their dietary choices, Datamonitor foresees a lot of untapped opportunities for the manufacturers to cater to in the future. Combo meal concepts which are microwaveable, for instance, would increase the overall value proposition offered by the RTE foods.

“Overall, the outlook for RTE foods in India looks quite promising, as all the necessary drivers to create a demand in the market for this kind of products is in place. Given manufacturers address the freshness and health-related issues, it could just be a matter of two to three years for this market to attain the critical mass, which would induce mass consumption in urban India”, concluded Pinaki.

Based on Datamonitor’s report ‘Emerging Opportunities in the Indian Ready-to-Eat Foods Market’ sent by Aartee Sundheep 17 May 2010

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Congolese soldiers learning self-sufficiency in food production

AFRICOM, Borlaug Institute lead agricultural initiative

KISANGANI -- The adage attributed to Napoleon Bonaparte that "an army travels on its stomach" is as true today as ever, according to participants in the Camp Base Agricultural Initiative in the Democratic Republic of the Congo.

The goal of this agriculture initiative, led by the United States African Command of the U.S. Department of Defense and the Norman Borlaug Institute of International Agriculture, is to show a battalion of U.S.-trained Congolese soldiers how to become self-sufficient in food production.

The site for this unique initiative is Camp Base outside Kisangani, the third-largest city in the Congo. The program began in October 2009 after receiving an initial year of funding, and key activities are anticipated to continue through October 2011.

Joey King, who administers the initiative, is chief of staff for the Borlaug Institute, part of the Texas A&M System and a key partner in the initiative. King said African militaries often cause instability in communities they are supposed to be protecting due to their need to poach food and other resources.

"It is important that these forces have systems for provisioning their own food even while operating in remote rural areas," he said.

Initiative efforts on the site will be focused on three general agricultural groupings – main crops, vegetables and livestock/fish farming. Cleared camp land will be prepared for agricultural production and for hands-on demonstrations of farming methods and techniques.

"Agriculture is a powerful tool in helping communities and countries prevent conflict and maintain stability," said Dr. Ed Price, director of the Borlaug Institute. "Increasing economic and social stability through food security is the first priority of this initiative. The second will be to help the battalion build food stockpiles which they can draw from during a deployment."

Initiative coordinators hope to enable the battalion to produce two to three months of provisions to use during deployment to conflict and post-conflict zones.

Price said providing the capability for the battalion to produce its own adequate, sustainable food supply would help "negate the need for the soldiers to raid local communities for supplies, increase their military effectiveness and improve the security of the area."

A large amount of land has already been cleared and is being prepared for agricultural development. In addition, dozens of soldiers from the 9th Military Region, along with "farm manager" candidates, are receiving ongoing agricultural education and training and hands-on experience.

One local agricultural engineer has been hired to help develop an educational curriculum for vegetable production and fish farming, plus to give hands-on training and provide oversight for camp agricultural efforts. In addition, a Congo-born Belgian, who has spent most of his professional life in the republic and is fluent in French, Swahili and Lingala, a regional Bantu language, has been hired as a technical consultant for the initiative.

Beau Davis, who lives in Kisangani, is the Borlaug Institute's in-country manager for the initiative. Since the initiative’s inception, he has been working with U.S. State Department and Department of Defense personnel, representatives of the U.S. Agency for International Development, the republic's Ministry of Agriculture, the University of Kisingani, International Institute for Tropical Agriculture, cassava producers and processors, and other individuals and organizations to develop and implement the initiative.

Most of his day-to-day contact, however, is with the soldiers supporting the initiative and individuals being trained as "farm managers" to provide more long-term initiative oversight.

"The 9th Military Region had a lieutenant serving as director of agriculture for this region," said Davis. "He used to operate a farm outside of Kisingani and was eager to work with the Borlaug Institute on the CBAI. His commanding general promised him a company of 50 men to support efforts by the initiative."

A separate agriculture unit was established, and soldiers from that unit provide the majority of the manpower toward camp agricultural development efforts, he said.

"While members of the unit are vital to fulfilling the short-term initiative goals, their military responsibilities may take them away from Kisingani after Borlaug Institute and AFRICOM initiative support ends. That's why we're also training a core group of 10 individuals who can be permanently based in Kisingani and serve as farm managers to sustain the initiative into the future."

Davis said some of the criteria set for potential farm managers were that they be "relatively young, educated, intelligent, motivated and have strong leadership potential."

"They will be in place as manager-trainers with knowledge they can pass along to soldiers and their families who will be stationed at the camp for years to come," he said. An initial five hectares (about 12.5 acres) have been cleared, plowed and are being planted with maize and cassava. A second five hectare plot, has been cleared for vegetable production and fish farming.

The first fish pond is under construction in an area which is spring fed, so it will not require a motorized pump.

"While some of the land we've been clearing had been farmed in the past three years, most was covered by thick vegetation and secondary forest," Davis said. "Battalion commanders have provided us with about 100 soldiers to help with the clearing.

Davis said there are daily competitions to recognize the hardest-working platoon, and the best platoon from each company is awarded with a package of sought-after items by the soldiers, including soap, shoe polish, razor blades and phone cards.

Preparations now are being made for planting half a hectare (about 1.25 acres) of tomatoes and half a hectare of amaranth, a local variety of spinach, and corn seed and cassava cuttings have been ordered for later planting. The rest of the initial site will be used for crop variety trials, including improved varieties of vegetables and maize. Peddle-powered pumps and portable sprinklers will allow for daily watering of seed beds and vegetable plants during dry months, enabling year-round production.

Davis said the “main crops” portion of the initiative will focus on maize and cassava as these are the staples of the region’s diet. Rice, cowpeas, groundnuts and other crops may be rotated in for future seasons.

"Cassava is the mainstay of the soldier's diet and can be produced in excess of their needs, so any excess can be sold to procure food items not produced by the initiative."

Davis said while most varieties of cassava require 12 months for harvest, some seven-month varieties will be planted to meet battalion food needs more quickly.

"Vegetables to be grown on site will include onions, peppers, tomatoes and plantains, and livestock production will be focused on goats and pigs, and there will be fish farming," he said.

Davis added that nitrogen-fixing varieties of native lucenia and acacia trees also may be planted at the camp since their leaves can be used as a food source for livestock. The trees could also be used to line driveways and camp boundaries and for sustainable charcoal production.

"This unique effort is not only a pioneering effort on behalf of AFRICOM, it provides a model that can be duplicated across the African continent," Price said. "The results of this initiative will bolster regional stability through improved food security and foster goodwill within the Democratic Republic of the Congo and the region at large."

Paul Schattenberg Texas A&M University System

May 27, 2010

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Saturated Fats Are Better Than Trans Fats: Panel

A panel of experts concluded that, while polyunsaturated or monounsaturated fats are the best replacements, a saturated fat is preferable to a trans fat in terms of cardiovascular disease risk.

It took two years to reach the conclusion in the headline. But in a "lesser of two evils" scenario, a panel of experts concluded that, while polyunsaturated or monounsaturated fats are the best replacements, a saturated fat is preferable to a trans fat in terms of cardiovascular disease risk.

A multidisciplinary panel of nutrition and clinical experts convened in late 2008 to review the science around possible solutions for replacement of trans fat and to discuss the implications for food manufacturers. "The group was comprised of individuals with very differing opinions, [so] the consensus was not actually reached until late 2009," said a spokesperson. "There were many smaller meetings and phone calls while the statement was nuanced and finally agreed upon by all involved. As you

know, the issue of trans fat replacement (saturated versus polys and monos, and palmitic versus stearic) is hotly debated, and it was discussed vigorously by all involved."

So it wasn't until earlier this year that the consensus statement was released: "Whenever possible, trans fats should be replaced with a polyunsaturated or monounsaturated fat. However, when a saturated fat is needed for functionality, it can be expected that overall cardiovascular disease risk would be improved compared to trans fats."

The panelists also explored other considerations in replacing trans fats, including how two saturated fat replacement solutions, palmitic acid and stearic acid, exert different effects on markers Participants of the roundtable are in the web version of this story, but they include medical doctors and high-profile nutrition professors. The panelists were:

- George Blackburn, MD - Associate Professor of Surgery and Nutrition, Associate Director of the Division of Nutrition, and first incumbent of the S. Daniel Abraham chair in Nutrition Medicine at Harvard Medical School
- Margo Denke, MD – formerly of University of Texas Southwestern Medical Center, Center for Human Nutrition; panel member on the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults convened by the National Heart, Lung and Blood Institute
- Richard Feinman, PhD of the State University of New York Downstate; director of the Nutrition & Metabolism Society and co-editor in chief of the Open Access online journal, Nutrition & Metabolism
- Christopher Gardner, PhD - associate research professor in the Department of Medicine at Stanford University and faculty in the Stanford Prevention Research Center
- KC Hayes, DVM, Ph.D., professor of biology (nutrition) and director of Foster Biomedical Research Laboratory and Animal Resources at Brandeis University
- Michael McBurney, PhD, FACN – formerly from Texas A&M's department of nutrition and food science and Kellogg Company
- Jeff Volek, PhD - associate professor in the Department of Kinesiology with an adjunct appointment in the Nutritional Sciences at the University of Connecticut.

From: Food Processing.Com May 2010

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Regulatory News

EFSA Concludes Safety of Ferrous Ammonium Phosphate as a Source of Iron

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the safety of Ferrous Ammonium Phosphate (FAP) when added for nutritional purposes in foodstuffs for particular nutritional uses (PARNUTS) and foods intended for the general population (including food supplements) as a source of iron and on the bioavailability of iron from this source.

The present opinion deals with the safety of FAP when added for nutritional purposes in PARNUTS and foods intended for the general population (including food supplements) as a source of iron and on the bioavailability of iron from this source. The safety of iron itself in terms of amounts that may be consumed is outside the remit of this Panel.

FAP is an inorganic salt with iron(II), ammonium and phosphate ions in a 1:1:1 molar ratio. The content of iron(II) is 22-30% (w/w).

The Panel notes that the representative commercial FAP product stability study for 19 and 36 months storage under the recommended conditions did not adequately confirm the stability of ferrous ion against oxidation.

From the stability studies in food and one in vitro solubility study under conditions mimicking the conditions in infant and adult stomachs, it can be deduced that FAP is stable at neutral pH in formulated foods but readily dissociates under the low pH conditions of the stomach, thus releasing the bioavailable ferrous ion.

The Panel reviewed a randomised double-blind, crossover human bioavailability study of iron from FAP. The bioavailability of iron from FAP was shown to be within the range of that from other iron salts used for fortification purposes, and specifically, less than that from ferrous sulphate and greater than that from ferric pyrophosphate.

The Panel notes that FAP is intended for use as a direct replacement for currently permitted iron forms in all PARNUTS food categories, with the exception of baby foods and infant formulae. The petitioner also proposed the use of FAP as a source of iron in fortified foods. The proposed conditions of use of FAP in intended food categories provides between 0.7 and 8.2 mg of iron per serving, which corresponds to between 5 and 58.6% of the Recommended Daily Amount (RDA) for iron in adults. FAP is also intended for use in food supplements as a direct replacement for other permitted sources of iron. One daily serving of FAP will not exceed the RDA for iron of 14 mg.

The Panel calculated the total dietary intake of iron, phosphorus and ammonia from the consumption of food categories fortified with FAP and from other dietary sources in European countries. The Panel assumed a daily intake of a beverage serving and a serving of solid food both fortified with FAP at the maximum proposed use levels for beverages (27.2 mg FAP per serving) and solid foods (14 mg FAP per serving) provided by the petitioner in the technical dossier.

The additional exposure to 12.4 mg iron/day from FAP (assuming 30% of iron content in a serving fortified with 41.2 mg FAP) would result in an anticipated total average exposure to iron ranging from 20.8 to 31.4 mg/day and at the high percentile in an anticipated exposure ranging from 25.2 to 43.3 mg/day for adults and an anticipated total average exposure ranging from 17.9 to 28.2 mg/day and at the high percentile in an anticipated exposure ranging from 20.7 to 39.4 mg/day for children. The Panel notes that the use levels of FAP proposed by the petitioner will provide 12 mg iron/day, which is below the guidance value for supplemental intake of iron of 17 mg/day recommended by the Expert Group on Vitamins and Minerals (EVM) in 2003. The proposed total exposure will not exceed the Provisional Maximum Tolerable Daily Intake (PMTDI) for iron established by Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1993, even in high consumers.

The Panel notes that an additional exposure to 22.7 mg phosphorus/day (assuming 55% of phosphorus content in a serving fortified with 41.2 mg FAP) would result in an anticipated total average exposure ranging from 1037.7 to 1838.7 mg/day and at the high percentile in an anticipated exposure ranging from 1525.7 to 2731.7 mg/day for adults and an anticipated total average exposure ranging from 942.7 to 1540.7 mg/day and at the high percentile in an anticipated exposure ranging from 1353.7 to 2593.7 mg/day for children. These amounts of phosphate do not exceed the
Tolerable Upper Intake Levels (ULs) defined by the Institute of Medicine (IOM) in 1997.

The intake of 3.7 mg ammonia/day from FAP (assuming 9% of ammonia content in a serving fortified at 41.2 mg FAP) seems negligible compared to its endogenous production levels of 3000 mg/day in the colon.

Studies evaluating the toxicity of FAP in experimental animals have not been conducted. In the study on the bioavailability of iron from FAP in humans, no gastrointestinal complaints or other adverse effects were reported following consumption of two servings of a milk product fortified with FAP, providing a total iron dose of 5 mg.

FAP dissociates at low pH to its respective ferrous, ammonium and phosphate ions. Given the previous evaluations of ferrous, ammonium and phosphate salts as food additives and as nutrient sources by the Scientific Committee on Food (SCF), EFSA and JECFA and that the available information on their toxicity did not identify toxicological effects, the Panel considers that additional toxicological data on FAP are not required.

The Panel notes that, at the proposed use levels, the corresponding exposure to iron from FAP does not exceed the guidance value for supplemental intake of iron of 17 mg /day recommended by the EVM. Likewise, the corresponding exposure to phosphorus from FAP does not exceed the ULs defined by the IOM and the ammonia exposure is negligible compared to its endogenous production level.

Therefore, the Panel concludes that the use of FAP as a source of iron in PARNUTS and in foods intended for the general population (including food supplements), at the proposed use levels, is not of safety concern provided that established upper safety limits for iron are not exceeded.

Nutrition Horizon 5 May 2010

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Joint SIDI Working Group Announces New Certificate of Analysis Guideline

The Joint Standardized Information on Dietary Supplement Ingredients (SIDI) Working Group a coalition of the dietary supplement industry's trade associations announced the release of the new Certificate of Analysis (CoA) Guideline, the latest in a series of voluntary guidelines for the supplement industry developed to assist finished product manufacturers with the complex process of qualifying their ingredient suppliers.

The voluntary CoA Guideline outlines the type and scope of information that should appear on a CoA provided by an ingredient supplier to its finished product manufacturer for a component or ingredient used in a dietary supplement.

"A requirement of the supplier qualification process involves verifying the information provided in an ingredient CoA, and manufacturers of dietary supplements rely on supplier CoAs to ensure finished products are GMP-compliant. It's essential for ingredient suppliers to have a form that can be consistently used, containing the appropriate information in a clear and concise format," said Andrew Shao, Ph.D., a spokesperson for the SIDI Working Group and CRN's senior vice president, scientific & regulatory affairs. "By standardizing the information on CoAs, this voluntary guideline will benefit both ingredient suppliers and dietary supplement manufacturers."

The voluntary CoA guideline, along with sample CoA templates for botanical and non-botanical ingredients, is available on the five trade associations' websites, along with the original SIDI protocol materials.

Council for Responsible Nutrition USA 20 May 2010

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Report Recommends Framework to Evaluate Science Behind Health Claims for Foods and Drugs

The U.S. Food and Drug Administration (FDA) should apply the same rigor to evaluating the science behind claims of foods' and nutritional supplements' health benefits as it devotes to assessing medication and medical technology approvals, says a new report from the Institute of Medicine.

There are no scientific grounds for using different standards of evidence when evaluating the health benefits of food ingredients and drugs given that both can have significant impacts on people's well-being, said the committee that wrote the report. It recommended a new framework the agency can use to consistently and transparently judge the appropriateness and validity of the scientific benchmarks used in studies that companies provide to support health and safety claims for their products.

Because it can be time-consuming and difficult to test products against actual clinical outcomes -- such as whether they cure or reduce the risk of a disease -- companies often conduct studies measuring effects on biomarkers, which are used as biological yardsticks or substitutes for clinical outcomes. For example, tumor size is used as a way to measure a cancer drug's effectiveness. Blood level of harmful cholesterol is often used as a biomarker for the risk of heart disease, and drug and food companies make claims about the heart health benefits of their products based on their ability to lower cholesterol levels, even if the products have not been shown to actually decrease heart disease.

FDA has been hampered in its ability to assess the proliferation of health claims being made by food and supplement manufacturers in part because it lacks a process broadly accepted across the regulatory, food, and medical communities to evaluate biomarkers as valid and appropriate measurements to substitute for clinical outcomes. The committee's proposed three-part framework gives the agency a way to consistently and rigorously assess the selection and use of biomarkers across the food, device, and drug areas.

In addition, the report calls on Congress to boost the agency's authority to require further studies of drugs and devices after they are approved if their approval is based on studies using biomarkers as surrogate clinical outcomes. And Congress should give FDA the authority to conduct studies of how well consumers understand food and supplement health claims and require manufacturers to make changes if needed to promote greater clarity.

"Many people naturally assume that the claims made for foods and nutritional supplements have the same degree of scientific grounding as those for medications, and this committee thinks that should in fact be the case," said committee chair John Ball, executive vice president, American Society for Clinical Pathology, Chicago. "Without changes in the way biomarkers are used and assessed, however, health care providers, regulators, and consumers will not be able to reliably collect or judge information to support claims. "

The proposed framework entails validating that a biomarker can be accurately measured, ensuring that it is associated with the clinical outcome of concern, and confirming that it is appropriate for the proposed use. Committee members demonstrated the kinds of information and lessons the framework can provide by doing several case studies, looking at tumor size as a biomarker for cancer, blood level of beta-carotene as a surrogate for cancer and cardiovascular disease risk, and cholesterol level as an indicator of heart disease, among others.

The report calls for Congress to enhance FDA's abilities to study how health-related information can be communicated more effectively to consumers to help them better understand the science behind claims they see on packaging. The typical consumer is not aware that claims for food ingredients and supplements are often made based on studies using biomarkers instead of actual health outcomes, and that this introduces a measure of uncertainty.

FDA also needs the resources and authority to act on claims when they are found to cause confusion or to exceed regulatory limits. A report issued by Rep. Henry Waxman's office noted that FDA enforcement of food and supplement health claims declined by more than 50 percent from 2000 to 2005. However, recent actions by the FDA indicate it is engaging in heightened enforcement of food labeling, including health claims.

The report was sponsored by the U.S. Food and Drug Administration. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies.

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