

Annexure - 1

Support for label claim on disease risk reduction on LeImmune-T

Natural Killer Cell mediated Innate Immunity Booster, LeImmune –T is an extract of tomato in edible oil and contain at least 418 µg β-carotene dissolved in oil in one day's dose as stipulated on the label of each batch. This amount of beta carotene dissolved in oil shall support an ingredient-led (β-carotene-led) label claim which reads as follows:

“There is Significant Scientific Agreement that beta carotene improves/restores activity of Natural Killer Cells activity in Innate Immunity compromised persons. Daily consumption of 200 g purple sweet potato leaves containing 23.42 mg β-Carotene improved the lytic activity of Natural Killer cells within 15 days in a human clinical trial (Chen et al.; World J Gastroenterol October 7, 2005 Volume 11 Number 37). From 56 molecules contained in green leafy vegetables, 1 molecule of beta carotene (that gives two molecules of Vitamin A) is bioavailable (GuangwenTang 2010; Am J Clin Nutr 2010;91(suppl):1468S–73S. Provitamin A carotenoids conversion factors (on a weight basis) is 28:1 with leafy vegetables). Thus, daily consumption of 418 µg of bioavailable β-Carotene improved the lytic activity of Natural Killer cells within 15 days in average individual.

Accordingly, “LeImmune-T”, an oil extract of tomato with at least 418 microgram of bioavailable beta-carotene in 5 ml. improves/restores activity of Natural Killer Cells/Innate Immunity (the First Line Immunity) capable destroying, without the need of prior vaccination, of destroying cells infected by any virus [Novel Coronavirus (SARS-CoV-2) is a virus], bacteria and initial stage solitary cancer cells before that pathogen/cancer cell gets an opportunity to multiply to give rise to the disease”.

LeImmune-T stands for the oil extract made form Tomato

This label claim complies with the regulation (8) recited in The Regulation as follows:

The regulation (8):

(8) To claim **ingredients**, nutrient or nutritional, **in respect of** an article of food for enhanced function and **disease risk reduction, regard shall be had to-**

- (i) claims that led to **ingredients** (nutrient or nutritional);
- (ii) **available scientific literature** including official traditional texts and post market data or consumer studies or cohort or **retroactive studies based on eating pattern and health benefits, epidemiological international and national data, and other well documented data;**
- (iii) consensual, congruent and concurrent validity studies;

(iv) **health promotive and disease risk reduction based on proof from literature and human data of efficacy and safety of the nutrient;**

(v) not only **controlled clinical trials** for efficacy and safety data; but also **nutraepidemiological data.**

“**LeImmune – T**” is an oil extract of tomato, which provides at least 418 µg β-carotene in 4g or less daily dose. The daily dose is indicated on the label of each batch.

Support from scientific literature is as follows for above highlighted elements:

Several references support Significant Scientific Agreement for improving Innate Immunity. They are provided as a list of references at the end. Content of some of them are quoted below with titles on the element they teach and our comments/interpretations after the quote.

1. **During the first critical hours and days of exposure to a new pathogen, we rely on our innate immune system ONLY to protect us from infection:**

<https://www.ncbi.nlm.nih.gov/books/NBK26846/> . “Humans are exposed to millions of potential pathogens daily, through contact, ingestion, and inhalation. Our ability to avoid infection depends in part on the adaptive immune system (discussed in Chapter 24), which remembers previous encounters with specific pathogens and destroys them when they attack again. Adaptive immune responses, however, are slow to develop on first exposure to a new pathogen, as specific clones of B and T cells have to become activated and expand; it can therefore take a week or so before the responses are effective. By contrast, a single bacterium with a doubling time of one hour can produce almost 20 million progeny, a full-blown infection, in a single day. **Therefore, during the first critical hours and days of exposure to a new pathogen, we rely on our innate immune system to protect us from infection.**

Innate immune responses are not specific to a particular pathogen in the way that the adaptive immune responses are. They depend on a group of proteins and phagocytic cells that recognize conserved features of pathogens and **become quickly activated to help destroy invaders.**”

Above reference points to two types of Immune systems. **Innate Immunity is the First Line Immunity**, which is not specific to a particular pathogen. This is followed by **Adaptive Immunity** which is Second Line Immunity because it is slow to develop on first exposure to a new pathogen and can therefore take a week or so before the responses are effective; and “the first exposure to new pathogens” means either a vaccination or getting sick by the attack of the pathogen and recovering thereafter. Products described simply as “Immunity Booster” relate to boosting Adaptive Immunity and an “**Innate Immunity Booster**” boosts Innate Immunity. Thus, an “Immunity Boosters” should accurately be described as “**Adaptive Immunity Boosters**”, which is useful to boost immunity against a virus only if it is adapted already by that person by virtue of prior vaccination or by recovering from sickness. Hence, “Immune Boosters” are not relevant

in the context of Novel Coronavirus for you until you have not got its vaccine or if you have not already been infected with this virus and have recovered from its attack.

In contrast, Innate Immunity Booster shall boost the Innate Immunity at optimum level and even if one is not vaccinated against a new virus/Novel Coronavirus, the new virus infected cell shall get destroyed within first critical hours and even if you have not taken a vaccine, risk of getting infected from Novel Coronavirus or any other virus gets substantially reduced. Additionally, risk of getting cancer is also reduced, because Innate Immunity detects cancer cells as “non-self” and uses same mechanism to destroy them which is sued for destroying virus infected cells.

2. **In elderly, Innate Immunity is compromised, but it is restored by β -carotene supplementation:**

Hughes (1999):

“Many epidemiological studies have shown an association between diets rich in carotenoids and a reduced incidence of many forms of cancer, and it has been suggested that the antioxidant properties of these compounds are a causative factor. Attention has focused on the potential role of one specific carotenoid, β -carotene, in preventing cancer, and numerous publications have described in vitro experiments and animal studies which suggest that not only can this carotenoid protect against the development of cancer, but also several other chronic diseases. Since the immune system plays a major role in cancer prevention, it has been suggested that β -carotene may enhance immune cell function. Several human trials, using dietary β -carotene supplementation with a wide range of intakes, have been undertaken to address this hypothesis. The general conclusion of these studies is that this compound can enhance cell-mediated immune responses, particularly in the elderly. -----”

“The antioxidant properties of carotenoids are thought to be a causative factor for the close association between diets rich in carotenoids and a reduced incidence of many forms of cancer (Block et al. 1992). In recent years, principally since the review article in **Nature** by Peto et al. (1981), a great deal of attention has focused on the potential role of one particular carotenoid, β -carotene (found in high amounts in carrots, broccoli and watercress (*Nasturtium officinale*), in preventing cancer. Numerous publications have described in vitro experiments, animal studies and **clinical trials** that suggest that this carotenoid cannot only protect against cancer, but also cardiovascular disease, stroke, aging, cataract and macular degeneration (for review, see Mayne, 1996). **Since the immune system plays a major role in the prevention of cancer, it has been suggested that β -carotene may enhance immune cell function.**”

This publication is a review that summarizes science published upto 1999 in peer reviewed journals, including such prestigious journals like **Nature** on science established

long back since at least from 1981, that **immune system plays a major role in the prevention of cancer, it has been suggested that β -carotene may enhance immune cell function.** This is a support that complies with requirements of Regulation (8) (i) (ii) (iv) and (v).

3. Clinical trial evidence that Natural killer cell activity in elderly men is enhanced by β -carotene supplementation:

Santos et al (1996):

In a cross-sectional, placebo-controlled, double-blind study we examined the effect of 10–12 y of beta-carotene supplementation (50 mg on alternate days) on NK cell activity in 59 (38 middle-aged men, 51–64 y; 21 elderly men, 65–86 y) Boston area participants in the Physicians' Health Study. ----- **beta-carotene-supplemented elderly men had significantly greater NK cell activity than elderly men receiving placebo.** The reason for this is unknown; however, it was not due to an increase in the percentage of NK cells, nor to an increase in interleukin 2 (IL-2) receptor expression, nor to IL-2 production. **beta-carotene may be acting directly on one or more of the lytic stages of NK cell cytotoxicity, or on NK cell activity-enhancing cytokines other than IL-2, such as IL-12. Our results show that long-term beta-carotene supplementation enhances NK cell activity in elderly men, which may be beneficial for viral and tumoral surveillance.**

This clinical trial provides evidence that β -carotene is the active agent that improved Natural Killer Cell activity in elderly men; who are immune-compromised persons and what happens in them shall happen in all other immune compromised persons. Other immune compromised persons includes children below 10 years age, persons of all ages who have diabetes and hypertension, persons who do strenuous duties which includes corona-warriors and persons who undertake high intensity physical activity such as marathon workers, body-builders etc.

4. There is NO clinical evidence so far for any active agent other than β -carotene to enhance the activity of Natural Killer Cells in Immune Compromised persons. **Hence, so far as current knowledge goes, unless a product described as Immune Booster contains effective quantity of bio-absorbable β -carotene; or a clinical evidence comes up that although there is absence of β -carotene that product improves activity of Natural Killer Cells, it cannot be called or used as "nate Immunity Booster".**
5. **Clinical trial evidence that Bioavailability of beta carotene was better when, instead of isolated crystalline beta carotene, the same was provided through a mixed fruit and vegetable dehydrated juice:**

Samman et al (2003):

Fruit and vegetable consumption is inversely associated with coronary heart disease (CHD) risk. The aim of the present study was to determine the effect of supplementation with dehydrated juice concentrates from mixed fruit and vegetables on selected plasma vitamins and antioxidant status. We assessed CHD risk by measuring the concentrations of homocysteine, lipids, lipoproteins, glucose and insulin. Men were recruited to participate in a **randomized double-blind, crossover trial with 2 periods of 6 wk, separated by a 3-wk wash-out period**. Supplementation with the encapsulated mixed extract (Juice Plus) was compared with physically similar placebo capsules. Thirty-two men (13 smokers, 19 nonsmokers) completed the study with a mean compliance of 88%. Compared with placebo, supplementation increased the concentrations of plasma beta-carotene (0.24 +/- 0.15 vs. 1.12 +/- 0.70 micro mol/L; mean +/- SD; P < 0.0001), retinol (1.87 +/- 0.33 vs. 2.00 +/- 0.43 micro mol/L; P < 0.05), alpha-tocopherol (16.8 +/- 7.3 vs. 19.3 +/- 6.8 micro mol/L; P < 0.01), ascorbic acid (72.1 +/- 19.4 vs. 84.1 +/- 13.5 micro mol/L; P < 0.002) and folic acid (24.5 +/- 10.0 vs. 44.9 +/- 16.9 nmol/L; P < 0.0001). Plasma homocysteine was reduced (8.2 +/- 1.5 vs. 7.6 +/- 1.1; P < 0.05) and inversely related (r = -0.40, P < 0.001) with serum folate concentrations. Plasma vitamin C was positively correlated with the resistance of LDL to oxidation (r = 0.26, P < 0.05) and the plasma ferric reducing/antioxidant power (FRAP) tended to be greater after supplementation than after the placebo period (1125.5 +/- 144.1 vs. 1180.3 +/- 158.1 micro mol/L; P < 0.065). Plasma glucose, insulin and lipid concentrations were unaffected. Responses of smokers and nonsmokers did not differ. In the absence of dietary modification, supplementation with a fruit and vegetable concentrate produced responses consistent with a reduction in CHD risk.

This clinical has shown that **bioavailability of beta carotene was better and resulted in decrease in risk of Cardiac Heart Disease** as indicated by decreased homocysteine level **when, instead of isolated crystalline beta carotene, the same was provided through a mixed fruit and vegetable dehydrated juice** at a rate of a dose of 12mg per day (which is also accompanied by presence of vitamin C, vitamin E and folic acid) in a double blind placebo controlled trial of two 6 week durations with a wash-out period of 3 weeks. **This trial had 13 smokers and 19 nonsmokers in the trial.** The dose used was also much smaller than 50 mg/day used for crystalline beta carotene in earlier reported prospective trials.

Thus, this trial has provided evidence that **beta carotene supplementation from food sources** provide clinical efficacy and isolated crystalline beta carotene is not required for the same. This is a useful result since crystalline beta carotene has poor bioavailability.

6. **A randomized crossover study evidence: Purple Sweet Potato leaves 200g per day for 20 days increased lytic activity of NK cells:**

Chen et al (2005):

METHODS: The randomized crossover study (two periods, each lasting for 2 wk) involved 16 healthy non-smoking adults of normal weight. The 6-wk study consisted of a run-in (wk 1) PSPL diet (daily consumption of 200 g PSPL) or a control diet (low polyphenols, with the amount of carotenoids adjusted to the same level as that of PSPL) (wk 2-3), washout diet (wk 4), and switched diet (wk 5-6). Fasting blood was collected weekly in the morning. T-lymphocyte function was assessed via the proliferation and secretion of immunoreactive cytokines. Salivary IgA secretion and the specific cytotoxic activities of cytotoxic T lymphocytes and natural killer (NK) cells were determined.

CONCLUSION: Consumption of PSPL modulates various immune functions including increased proliferation responsiveness of PBMC, secretion of cytokines IL-2 and IL-4, and the lytic activity of NK cells.

PSPL-related daily dietary intake was 902 mg GAE of total polyphenol and 23.42 mg of β -carotene. Control subjects ingested the same amount of β -carotene from 40 to 45 g carrots (268.76 μ g/g of β -carotene) each day.

7. **Beta carotene content of Purple Sweet Potato leaves:**

- a. <https://www.uaex.edu/publications/PDF/FSA-6135.pdf>

[Shahidul Islam](#)

Depending on varieties and growing conditions, sweet potato leaves are comparable to spinach in nutrient content, The average mineral and vitamin content in a recently developed cultivar, Suioh, is 117mg calcium, 1,8 mg iron, 3.5 mg carotene, 87.2 mg vitamin C, 1,6 mg vitamin E and 0,56 mg vitamin K/100 g fresh weight of leaves.

- b. [https://www.healthbenefitstimes.com/health-benefits-of-sweet-potato-leaves/.](https://www.healthbenefitstimes.com/health-benefits-of-sweet-potato-leaves/)

35 g Sweet Potato leaves contain 776 μ g β -Carotene.

- c. **Tang Guangwen (2010)**

Bioavailability of beta carotene, in terms of beta carotene consumed through food sources to its conversion to Vitamin A is affected by food matrix. **Table 1 shows that when beta carotene is sourced in diet from Green Leafy Vegetables, this conversion factor by weight, in three cases is 26:1, 27:1 and 28:1.**

To be conservative, for Sweet Potato Leaves, the factor is considered to be 28:1. This means, when 28mg of beta carotene is fed, one mg of Vitamin A is seen in serum arising from this feeding. Since one molecule of beta carotene makes two molecules of vitamin A, that molecule has to be the one that is bio-absorbed from the beta carotene fed through the green leafy vegetable. Hence, for bio-absorption of one molecule of beta carotene, 56 molecules of beta carotene should be fed through green leafy vegetable. Hence, in terms of bio-absorbable beta carotene the ratio is 56:1 by weight.

Thus, in view of the beta carotene content in Purple Sweet Potato leaves as provided by Cheg et al. is 23.42mg in 200 gram leaves, the bio-absorbable beta carotene from 200g Sweet Potato Leaves shall be $23420/56 = 418 \mu\text{g } \beta\text{-Carotene}$.

In conclusion, based on clinical trial of Chen et al (2005), consumption of a human being of 418 μg of bioavailable $\beta\text{-Carotene}$ shall modulate various immune functions including increased proliferation responsiveness of PBMC (peripheral blood mononuclear cell), secretion of cytokines IL-2 and IL-4, and the lytic activity of NK cells **within a span of two weeks**. The lytic activity of NK cells modulated Innate Immunity shall lyse a cell infected by ANY virus, old as well as Novel; **including 2019 Novel Coronavirus**.

8. **Since the active ingredient is $\beta\text{-Carotene}$, the $\beta\text{-Carotene}$ sources from any food source would give the effect of modulating Innate Immunity.**
9. **Clinical trial: $\beta\text{-carotene}$ is absorbable only when it is transferred to fat phase of the meal:**

Tyssandier (2003)

Carotenoids are thought to diminish the incidence of certain degenerative diseases, but the mechanisms involved in their intestinal absorption are poorly understood. Our aim was to obtain basic data on the fate of carotenoids in the human stomach and duodenum. Ten healthy men were intragastrically fed three liquid test meals differing only in the vegetable added 3 wk apart and in a random order. They contained 40 g sunflower oil and mashed vegetables as the sole source of carotenoids. Tomato purée provided 10 mg lycopene as the main carotenoid, chopped spinach (10 mg lutein), and carrot purée (10 mg beta-

carotene). Samples of stomach and duodenal contents and blood samples were collected at regular time intervals after meal intake. all-trans and cis carotenoids were assayed in stomach and duodenal contents, in the fat and aqueous phases of those contents, and in chylomicrons. The cis-trans beta-carotene and lycopene ratios did not significantly vary in the stomach during digestion. Carotenoids were recovered in the fat phase present in the stomach during digestion. **The proportion of all-trans carotenoids found in the micellar phase of the duodenum was** as follows (means +/- SE): lutein (5.6 +/- 0.4%), **beta-carotene (4.7 +/- 0.3%)**, lycopene (2.0 +/- 0.2%). The proportion of 13-cis beta-carotene in the micellar phase was significantly higher (14.8 +/- 1.6%) than that of the all-trans isomer (4.7 +/- 0.3%). There was no significant variation in chylomicron lycopene after the tomato meal, whereas there was significant increase in chylomicron beta-carotene and lutein after the carrot and the spinach meals, respectively. **There is no significant cis-trans isomerization of beta-carotene and lycopene in the human stomach. The stomach initiates the transfer of carotenoids from the vegetable matrix to the fat phase of the meal.** Lycopene is less efficiently transferred to micelles than beta-carotene and lutein. **The very small transfer of carotenoids from their vegetable matrices to micelles explains the poor bioavailability of these phytomicroconstituents.**

This reference establishes that β -carotene dissolved in fat is bio-absorbable/bio-available. Any other form of β -carotene is poorly bio-absorbable. Hence, we decided to make an oil extract of food source that has reasonably good content of β -carotene, so that whatever is the content by chemical analysis, that much shall be 100% bio-available/bio-absorbable.

10. **NK cells have been shown to possess traits of adaptive immunity:**

O'Sullivan (2015)^a

Natural killer (NK) cells have historically been considered short-lived cytolytic cells that can rapidly respond against pathogens and tumors in an antigen-independent manner and then undergo cell death. **Recently, however, NK cells have been shown to possess traits of adaptive immunity and can acquire immunological memory in a manner similar to that of T and B cells.** In this review, we discuss evidence of NK cell memory and the mechanisms involved in the generation and survival of these innate lymphocytes.

O'Sullivan (2015)^b

Immunological memory is classically regarded as an attribute of antigen-specific T and B lymphocytes of the adaptive immune system. Cells of the innate immune system, including natural killer (NK) cells, have been considered short-lived

cytolytic cells that can rapidly respond against pathogens in an antigen-independent manner and then die off. However, **NK cells have recently been described to possess traits of adaptive immunity, such as clonal expansion after viral antigen exposure to generate long-lived memory cells.** In this review, we will discuss the current evidence for viral-induced NK cell memory in both mice and humans.

Above two references of O’Sullivan are a very important advance in knowledge about Natural Killer Cell mediated Innate Immunity, which also includes. Now, Adaptive Immunity too; and provides a material advance in public health strategy to combat/control an epidemic or a pandemic.

This means that on one hand vaccine shall have an advantage that it shall be very very specific to the Novel Coronavirus or any novel pathogenic virus, and is conservatively regarded as THE only tool against a new pathogen, it should be pursued for development in any case, however,

- health authorities do not have to wait for the vaccine to develop and reach up to the people; they can, as first step against an epidemic or a pandemic, immediately orally administer Innate Immunity Booster to Innate Immunity compromised persons, who are the main section of people who become links of chain of spread of the infection; and if the link is broken soon, the epidemic/pandemic will get controlled that much soon. Rather, once Innate Immunity of Innate Immunity compromised people gets restored in about two weeks, if they get an exposure to the Novel Coronavirus, their cells infected by the first exposure will get destroyed by their improved Innate Immunity in first few hours so that they do not develop sickness; and that exposure of Novel Coronavirus will also trigger generation of anti-bodies against that strain of Novel Coronavirus (which may be termed as “Natural Vaccination” which is very safe and may also not involve the fever and other sufferings that may be associated with the artificial vaccine against Coronavirus); leading to development of Adaptive Immunity WITHOUT the need of waiting for the vaccine to reach up to them. Of course, even after developing such adaptive immunity against the Novel Coronavirus, as and when the vaccine reaches them, as an abundant precaution, they should take that also as an additional Second Line of Protection.
- Whereas the vaccine against Novel Coronavirus shall give protection against ONLY the Novel Coronavirus strain from which it has been generated, Innate Immunity Booster will provide protection against any new mutation of the same that may not be controlled by the already developed vaccine, or also against ANY new pathogenic Novel Virus; and additionally against cancer too.
- Oral administration of Immune Immunity Booster

- (a) Since tomato is currently more easily available in good quantity in India, it was selected to make its **oil extract** and **its daily dose is selected to provide at least 418 µg β-**

carotene per day; and its daily consumption **would improve the level of Natural Killer Cells activity/Innate Immunity to optimum** level in adults **in two weeks**.

- (b) Oil extract of heat precipitated coagulum of juice of green leafy vegetables is also made, which contains, in one day dose, at least 418 µg β-Carotene; and the product is named as LeImmune-G.
- (c) LeImmune-T/LeImmune-G, which contains at least 418µg of 100% Bioavailable β-Carotene in a daily dose as provided in label provide “Reduction in the Risk of Infections from microbes, including novel Coronavirus”.

11. <https://www.aviva.co.uk/health-insurance/home-of-health/latest-news/story/801747741/cancer-researchers-highlight-importance-of-natural/> :

Specialised immune cells known as natural killer cells could be used to help destroy cancers that are in the process of spreading to other areas of the body.

As pointed out by Hughes above, destroying cancers is done by Natural Killer Cells; and the same cells are shown above to be able to destroy novel pathogenic viruses in first few hours of their invading our cells i.e. before they start multiplying and are able to cause systemic infection and disease in the body.

12. <http://www.ars.usda.gov/News/docs.htm?docid=23199>

“----- carotenoids—antioxidants that protect cells and play roles in blocking the early stages of cancer----- “

“Because of their high content of antioxidants, green leafy vegetables may be one of the best cancer-preventing foods. Studies have shown that eating 2 to 3 servings of green leafy vegetables per week may lower the risk of stomach, breast and skin cancer. These same antioxidants have also been proven to decrease the risk of heart disease.”

13. American Institute for cancer Research in its link

http://www.aicr.org/foods-that-fight-cancer/foodsthatfightcancer_leafy_vegetables.html

provides information on foods that fight cancer.

American Institute for cancer Research acknowledges that:

“Foods That Fight Cancer

Dark Green Leafy Vegetables

“Spinach, kale, romaine lettuce, leaf lettuce, mustard greens, collard greens, chicory and Swiss chard are excellent sources of **fiber**, **folate** and a wide range of **carotenoids** such as lutein and zeaxanthin, along with saponins and flavonoids.

According to AICR's second expert report, *Food, Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective*, foods containing carotenoids probably protect against cancers of the mouth, pharynx and larynx.

Researchers believe that carotenoids seem to prevent cancer by acting as antioxidants – that is, scouring potentially dangerous “free radicals” from the body before they can do harm. Some laboratory research has found that the carotenoids in dark green leafy vegetables can inhibit the growth of certain types of breast cancer cells, skin cancer cells, lung cancer and stomach cancer.”

14. Chiu et al on the link <http://www.ncbi.nlm.nih.gov/pubmed/21695384>[Dietary intake of fruit and vegetables and risk of non-Hodgkin lymphoma. Chiu BC¹, Kwon S, Evens AM, Surawicz T, Smith SM, Weisenburger DD.]

have confirmed that:

“a higher intake of greenleafyvegetables and cruciferous vegetables is associated with a lower risk of NHL overall, particularly follicular lymphoma and DLBCL.”

15. Carter et al on the link <http://www.ncbi.nlm.nih.gov/pubmed/20724400> BMJ. 2010 Aug 18;341:c4229. doi: 10.1136/bmj.c4229.

Carter P¹, Gray LJ, Troughton J, Khunti K, Davies MJ. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2924474/> [Fruit and vegetable intake incidence of type 2 diabetes mellitus: systematic review and meta-analysis.]:

They have further elucidated Potential benefits of green leafy vegetables that:

“A possible benefit of fruit and vegetables in the prevention of chronic diseases is from their antioxidant content and thus a contribution to reduction of systemic oxidative stress.”

They confirmed that their results support this as green leafy vegetables, such as spinach, have been shown to contain **high concentrations of β carotene** and vitamin C, both of which confer antioxidant properties. Green leafy vegetables also contain poly phenols, which are known for their antioxidant properties.

Green leafy vegetables are also good sources of α linolenic acid, which is an omega 3 polyunsaturated fatty acid. The fatty acid profile of the diet is thought to be important in determining the fatty acid composition of the phospholipid bilayer. The composition of this bilayer is related to insulin sensitivity within skeletal muscle. **Thus there are several possible mechanisms that could explain the benefit of consuming green leafy vegetables in the diet.**

16. Zhang CX¹, Ho SC, Chen YM, Fu JH, Cheng SZ, Lin FY. [Int J Cancer. 2009 Jul 1;125(1):181-8. doi: 10.1002/ijc.24358. Greater vegetable and fruit intake is associated with a lower risk of breast cancer among Chinese women. (<http://www.ncbi.nlm.nih.gov/pubmed/19358284>):

“Total vegetable and fruit intake was found to be inversely associated with breast cancer risk. Consumption of individual vegetable and fruit groups such as **dark green leafy vegetables**, cruciferous vegetables, carrots and tomatoes, banana, watermelon/papaya/cantaloupe were all inversely and significantly related with breast cancer risk. An inverse association was also observed for **vitamin A, carotene, vitamin C, vitamin E, and fiber intake**. These data indicate that greater intake of vegetables and fruits is **associated with a decreased risk of breast cancer** among Chinese women residing in Guangdong.”

17. Agte et al (2006) on the link <http://www.ncbi.nlm.nih.gov/pubmed/15834756> [Eur J Nutr. 2006 Feb;45(1):29-36. Epub 2005 Apr 20. GLV supplements increased plasma beta-carotene, vitamin C, zinc and hemoglobin in young healthy adults. Agte V¹, Jahagirdar M, Chiplonkar S.] have confirmed that

“Green leafy vegetables (GLV) are rich sources of beta-carotene, iron and other micronutrients. Our in vitro studies have demonstrated good antioxidant potential in GLV. Moreover linkages of GLV intakes with plasma retinol and ascorbic acid were seen in apparently healthy Indians.

“Using 100 g GLV/day with 10 g oil could be a single moderate strategy for supplementation of iron, beta-carotene, ascorbic acid and zinc”

18. Van het Hof KH¹, Tijburg LB, Pietrzik K, Weststrate JA. Influence of feeding different vegetables on plasma levels of carotenoids, folate and vitamin C. Effect of disruption of the vegetable matrix. Br J Nutr. 1999 Sep;82(3):203-12 (<http://www.ncbi.nlm.nih.gov/pubmed/10655967>):

“in case of consumption of 300 g/day of different vegetables, Carotenoids, folate and vitamin C may contribute to the observed beneficial effects of increased vegetable intake; currently, knowledge on the *bioavailability of these compounds from vegetables is limited*; and disruption of the vegetable matrix would enhance the bioavailability of carotenoids, folate and vitamin C. We compared the efficacy of different vegetables, at the same level of intake (i.e. 300 g/d), ----- **We conclude that the bioavailabilities of beta-carotene and lutein vary substantially among different vegetables and that the bioavailabilities of lutein and folate from spinach can be improved by disruption of the vegetable matrix.”**

19. Castenmiller JJ¹, West CE, Linssen JP, van het Hof KH, Voragen AG. The food matrix of spinach is a limiting factor in determining the bioavailability of beta-carotene and to a lesser extent of lutein in humans 1999 Feb;129(2):349-55. (<http://www.ncbi.nlm.nih.gov/pubmed/10024612> [J Nutr.):

“Carotenoid bioavailability depends, amongst other factors, on the food matrix and on the type and extent of processing.

20. van het Hof KH¹, Brouwer IA, West CE, Haddeman E, Steegers-Theunissen RP, van Dusseldorp M, Weststrate JA, Eskes TK, Hautvast JG Bioavailability of lutein from vegetables is 5 times higher than that of beta-carotene. 1999 Aug;70(2):261-8. (<http://www.ncbi.nlm.nih.gov/pubmed/10426704> [Am J ClinNutr.):

“To gain more insight into the relation between vegetable consumption and the risk of chronic diseases, it is important to determine the bioavailability of carotenoids from vegetables and the effect of vegetable consumption on selected biomarkers of chronic diseases.

21. Fröhlich RH and Kunze (1997) on the link: <http://www.ncbi.nlm.nih.gov/pubmed/9312973> [Acta Med Austriaca. 1997;24(3):108-13. Cancer preventive value of natural, non-nutritive food constituents].] have reported that:

“Numerous epidemiologic studies have shown that a diet rich in vegetables, fruits and fiber is associated with a decreased risk of cancer, particularly of epithelial tumors. Especially this association is evident for various citrus fruits, carrots, leafygreenvegetables, as well as cruciferous-(sorts of cabbage, broccoli) and leak vegetables (garlic, onions, etc.). In the course of investigation of the protective mechanisms exerted by vegetable foodstuffs, a great number of secondary plant products such as carotenoids, sulfides, glucosinolates, plant sterols saponins, terpens, phytoestrogens, flavones, protease inhibitors, or phenolic acids, which are substantial constituents of our daily food, have changed their meaning from a non-nutritive constituent to a

probably cancer preventive biological-active substance. But also fermentable, soluble fibers and substances in fermented foods can exert protective effects on development of cancer. **Mostly the anticarcinogenic action of biological-active substances is limited to an early stage of carcinogenesis. Therefore it seems to be important to start prevention of cancer by nutrition as early as possible and adhere to it over a long period.**

22. Potter and Steinmetz (1996) on the link: <http://www.ncbi.nlm.nih.gov/pubmed/8923020> [IARC Sci Publ. 1996;(139):61-90. Vegetables, fruit and phytoestrogens as preventive agents. Potter JD¹, Steinmetz K.] have reported that:

“----- Review of the epidemiological data, including both cohort and case-control studies, of all cancer sites strongly suggests that plant foods also have preventive potential and that consumption of the following groups and types of vegetables and fruits is lower in those who subsequently develop cancer: raw and fresh vegetables, leafygreenvegetables, Cruciferae, carrots, broccoli, cabbage, lettuce, and raw and fresh fruit (including tomatoes and citrus fruit). ----- There are many biologically plausible reasons why consumption of plant foods might slow or prevent the appearance of cancer. These include the presence in plant foods of such potentially anticarcinogenic substances as carotenoids, vitamin C, vitamin E, selenium, dietary fibre (and its components), dithiolthiones, isothiocyanates, indoles, phenols, protease inhibitors, allium compounds, plant sterols, and limonene. ----- For example, ----- phenols, and coumarins can induce a multiplicity of phase II (solubilizing and usually inactivating) enzymes; ascorbate and phenols block the formation of carcinogens such as nitrosamines; flavonoids and carotenoids act as antioxidants, essentially disabling the carcinogenic potential of specific compounds; lipid-soluble compounds such as carotenoids and sterols may alter membrane structure or integrity; ----- carotenoids can suppress DNA synthesis and enhance differentiation----- Consumption of diets low in plant foods results in a reduced intake of a wide variety of those substances that can plausibly lower cancer risk. In the presence of a diet and lifestyle high in potential carcinogens (whether derived from fungal contamination, cooking or tobacco) or high in promoters (such as salt and alcohol), overall risk of cancer at many epithelial sites is elevated. **Plant foods appear to exert a general risk-lowering effect; the patterns of exposure to cancer initiators and promoters and of genetic susceptibility may determine the variations in the site-specific risks of cancer seen across populations.**

23. Steinmetz and Potter (1991) on the link: <http://www.ncbi.nlm.nih.gov/pubmed/1764568> [Cancer Causes Control. 1991 Nov;2(6):427-42. Vegetables, fruit, and cancer. II. Mechanisms. Steinmetz KA¹, Potter JD.] have provided an extensive discussion on mechanisms of disease risk reduction as follows:

“The epidemiologic literature on the relationship between vegetable and fruit consumption and human cancer at a variety of sites was reviewed systematically in Part I. **It was concluded that consumption of higher levels of vegetables and fruit is associated consistently,** although not universally, **with a reduced risk of cancer at most sites, and particularly with epithelial cancers of the alimentary and respiratory tracts.** Possible mechanisms by which vegetable and fruit intake might alter risk of cancer are addressed here. A large number of **potentially anticarcinogenic agents are found in these food sources, including carotenoids, vitamins C and E, selenium,** dietary fiber, dithiolthiones, glucosinolates and indoles, isothiocyanates, **flavonoids, phenols,** protease inhibitors, plant sterols, allium compounds, and limonene. **These agents have both complementary and overlapping mechanisms of action,** including the induction of detoxification enzymes, inhibition of nitrosamine formation, provision of substrate for formation of antineoplastic agents, **dilution and binding of carcinogens in the digestive tract,** alteration of hormone metabolism, **antioxidant effects,** and others. **It appears extremely unlikely that any one substance is responsible for all the associations seen.** Possible adverse effects of vegetable and fruit consumption are also examined. One way to consider the relationships reviewed here is to hypothesize that **humans are adapted to a high intake of plant foods that supply substances crucial to the maintenance of the organism, but only some of which are currently called 'essential nutrients.'** **Cancer may be the result of reducing the level of intake of foods that are metabolically necessary--it may be a disease of maladaptation.”**

24. Waladkhani and Clemens (1998) on the link: <http://www.ncbi.nlm.nih.gov/pubmed/9852292> [Int J Mol Med. 1998 Apr;1(4):747-53. Effect of dietary phytochemicals on cancer development (review) Waladkhani AR¹, Clemens MR.] find that:

“Vegetables, fruits, and whole grains contain a wide variety of phytochemicals that have the potential to modulate cancer development. There are many biologically plausible reasons why consumption of plant foods might **slow or prevent the appearance of cancer.** These include the presence in plant foods of such potentially anticarcinogenic substances as **carotenoids, chlorophyll, flavonoids,** indole, isothiocyanate, **polyphenolic compounds,** protease inhibitors, sulfides, and terpenes. The specific mechanisms of action of most phytochemicals in cancer prevention are not yet clear but appear to be varied. Considering the large number and variety of dietary phytochemicals, their interactive effects on cancer risk may be extremely difficult to assess. **Phytochemicals can inhibit carcinogenesis by inhibiting phase I enzymes, and induction of phase II enzymes, scavenge DNA reactive agents, suppress the abnormal proliferation of early, preneoplastic lesions, and inhibit certain properties of the cancer cell.”**

25. Eriksen et al (2016) on the link: <http://www.ncbi.nlm.nih.gov/pubmed/26948584> [Food Chem. 2016 Jul 15;203:23-7. doi: 10.1016/j.foodchem.2016.02.033. Epub 2016 Feb 4. In vitro liberation of carotenoids from spinach and Asia salads after different domestic kitchen procedures. Eriksen JN¹, Luu AY², Dragsted LO², Arrigoni E³.] provide the information that:

“Green-leafy vegetables are rich in nutritionally important constituents including carotenoids. Their potential health benefits depend among others on their liberation from the plant matrix. The aim of the present study was to evaluate the effect of particle size and heat treatments on lutein and β -carotene liberation from spinach and Asia salads by applying an in vitro digestion protocol and UHPLC analysis. Reduction of particle size resulted in a three- to fourfold increase in liberation of lutein and β -carotene when comparing whole leaf and puree preparations of spinach. However, this positive effect was shown to be nullified by the severe heat impact during stir-frying of minced spinach, showing that domestic treatments need to be chosen carefully to maximise carotenoid liberation. Steaming significantly improved lutein liberation from Asia salads, but had no or a negative effect in spinach samples, possibly due to differences in liberation or degradation between the two plant matrices.”

26. Tyssandier et al (2003) on the link: <http://www.ncbi.nlm.nih.gov/pubmed/12736146>[Am J PhysiolGastrointest Liver Physiol. 2003 Jun;284(6):G913-23. Epub 2003 Jan 10. Processing of vegetable-borne carotenoids in the human stomach and duodenum.Tyssandier V¹, Reboul E, Dumas JF, Bouteloup-Demange C, Armand M, Marcand J, Sallas M, Borel P.] have reported that:

“Carotenoids are thought to diminish the incidence of certain degenerative diseases, but the mechanisms involved in their intestinal absorption are poorly understood. Our aim was to obtain basic data on the fate of carotenoids in the human stomach and duodenum. Ten healthy men were intragastrically fed three liquid test meals differing only in the vegetable added 3 wk apart and in a random order. They contained 40 g sunflower oil and mashed vegetables as the sole source of carotenoids. Tomato purée provided 10 mg lycopene as the main carotenoid, chopped spinach (10 mg lutein), and carrot purée (10 mg beta-carotene). Samples of stomach and duodenal contents and blood samples were collected at regular time intervals after meal intake. all-trans and cis carotenoids were assayed in stomach and duodenal contents, in the fat and aqueous phases of those contents, and in chylomicrons. **The cis-trans beta-carotene and lycopene ratios did not significantly vary in the stomach during digestion. Carotenoids were recovered in the fat phase present in the stomach during digestion.** The proportion of all-trans carotenoids found in the micellar phase of the duodenum was as follows (means +/- SE): lutein (5.6 +/- 0.4%), beta-carotene (4.7 +/- 0.3%), lycopene (2.0 +/- 0.2%). The proportion of 13-cis beta-carotene in the micellar phase was significantly higher (14.8 +/- 1.6%) than that

of the all-trans isomer (4.7 +/- 0.3%). There was no significant variation in chylomicron lycopene after the tomato meal, whereas there was significant increase in chylomicron beta-carotene and lutein after the carrot and the spinach meals, respectively. There is no significant cis-trans isomerization of beta-carotene and lycopene in the human stomach. **The stomach initiates the transfer of carotenoids from the vegetable matrix to the fat phase of the meal. Lycopene is less efficiently transferred to micelles than beta-carotene and lutein. The very small transfer of carotenoids from their vegetable matrices to micelles explains the poor bioavailability of these phytomicroconstituents.**

27. Tyssandier et al (2002) on the link: <http://www.ncbi.nlm.nih.gov/pubmed/11864859> [Am J Clin Nutr. 2002 Mar;75(3):526-34. Vegetable-borne lutein, lycopene, and beta-carotene compete for incorporation into chylomicrons, with no adverse effect on the medium-term (3-wk) plasma status of carotenoids in humans. Tyssandier V¹, Cardinault N, Caris-Veyrat C, Amiot MJ, Grolier P, Bouteloup C, Azais-Braesco V, Borel P.] found that:

“The results of epidemiologic studies have consistently shown associations between dietary intake or plasma carotenoid status and incidence of cancers and cardiovascular and eye diseases.

The aim was to assess whether vegetable-borne carotenoids (lycopene, lutein, and beta-carotene) compete for intestinal absorption and whether this affects the plasma status of carotenoids in the medium term (ie, after 3 wk).

CONCLUSION:

Consumption of carotenoids from different vegetable sources does not diminish plasma carotenoid concentrations in the medium term, despite the finding in postprandial testing of competitive inhibitory interactions among different carotenoids.”

28. Davys et al (2014) on the link: <http://extraits-foliaires-en-nutrition.org/wp-content/uploads/2014/02/12-10-FAO-paper-Chapter-18.pdf> [18 Leaf Concentrate and Other Benefits of Leaf Fractionation.] have reviewed extensively the health benefits and various feeding trials that support the health benefits available for Leaf protein concentrate, which are summarized as follows, details being available on the above link:

Leaf concentrate is an extremely nutritious human food, containing approximately 50% (dry weight) high quality protein, together with numerous micronutrients, principally b-

carotene, vitamins B6, B9, E and K, plus iron, calcium and magnesium. Many studies have shown that those consuming it recover quickly from nutritional anaemia and have a significantly improved general state of health. Today, over 40,000 people receive a daily serving of 10g of dried lucerne leaf concentrate. The fractionation of leaves was first reported over 200 years ago and has been the subject of extensive research and application since the 1940s. The process breaks down the original leaves into three products: residual fibre, 'whey' and leaf concentrate. The whey and the fibre are effective fertilizers, substrates for fermentation and/or animal feed. Through the use of all three products, leaf fractionation can be more productive, in terms of edible protein per hectare of land, than any other known agricultural method.

Summary: There is significant scientific agreement that:

1. Natural Killer Cell mediated Innate Immunity system has capability to destroy cells infected by ANY virus within first few hours of infection when the virus is yet to start multiplying; and this action does not need prior introduction or vaccination with that virus.
2. Novel Coronavirus ((SARS-CoV-2)) that causes COVID-19 comes within the scope of ANY Virus.
- 3.

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4. Chiu et al on the link <http://www.ncbi.nlm.nih.gov/pubmed/21695384>[Dietary intake of fruit and vegetables and risk of non-Hodgkin lymphoma. Chiu BC¹, Kwon S, Evens AM, Surawicz T, Smith SM, Weisenburger DD.]
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