

REGULATIONS ON FORTIFIED MILK

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Introduction

As per Food Safety and Standards Regulations, 2011, **MILK** is the normal mammary secretion derived from complete milking of healthy milch animal without either addition thereto or extraction therefrom unless otherwise provided in these regulations. It shall be free from colostrum. Total urea content in the milk shall not be more than 700 ppm.

Though there are regulations on fortified atta and fortified maida, there is no regulation on fortified milk in FSSR, 2011. The term **fortification** means the addition of nutrients at levels higher than those found in the original food. Milk is fortified usually by **Vitamins A and D and by Iron**.



Need for Fortification

- Early in the 20th century, more than 80% of children in Europe and North America were suffering from Rickets. Finding that exposure to ultraviolet radiation or sunlight treated and prevented Rickets led to the ultraviolet irradiation of foods including milk. Many countries mandated the fortification of milk with Vitamin D to prevent rickets. The most cost effective way is to increase food fortification with higher levels of Vitamin D along with sensible sun exposure.
- Because most foods contain only very low amounts of Vitamin D , it is the practice in many countries to fortify certain frequently consumed foods (e.g., baked goods, grain products, milk, yogurt, cheese, margarines, orange juice, infant foods and some breads). In the late 1950s, the American Medical Association recommended that milk be fortified with 400 IU (10 mcg) per quart. The USFDA has specified that milk should contain 400 - 600 IU / qt. However, most European countries do not fortify milk with Vitamin D.

Significance of Vitamin D

- Vitamin D , "**the sunshine vitamin**", is actually a hormone produced from sterols in the body by the photolytic action of ultraviolet light on the skin. Individuals who receive modest exposures to sunlight are able to produce their own Vitamin D. But this is not the case for many people.
- Vitamin D plays an important role in the maintenance of healthy bones and teeth along with the essential minerals calcium , phosphorus and magnesium. An estimated 40 - 90% of adults worldwide are of insufficient Vitamin D status. Rickets, the deforming of the long bones, remain a problem in many countries. Prevalences as high as 10% has been reported among breast fed infants and children with little sun exposure.



Sources of Vitamin D

- Vitamin D indicates either Vitamin D2 (ergo calciferol) or Vitamin D3 (cholecalciferol).
- Vitamin D is sparsely represented in nature but its provitamins are common in both plants and animals.
- Vitamin D2 is present only in small amounts in nature.
- Vitamin D3 is widely distributed in animals but has extremely limited distribution in plants. In animals, tissue cholecalciferol concentrations are dependent on the Vitamin D3 content of the diet and/ or exposure to sunlight.
- Few foods particularly fish liver and oils are rich sources of Vitamin D3 which occurs in those materials in free form as well as esters of long chain fatty acid esters. Fish oils have Vitamin D3 concentrations of about 50 mcg / g but cod, tuna, mackerel oils contain 20 times that level. Oily fishes can provide significant amounts of Vitamin D. Farm raised fish may not contain significant amounts of Vitamin D unless it has been added as a supplement to the formulated feed. With a few exceptions, Vitamin D3 is not found in plants.

Vitamin D activities in Foods

In general, the chief food sources of Vitamin D are fortified milk and fatty fish. Vitamin D can also be obtained from nutritional supplements. Multivitamin supplements typically contain 400 IU Vitamin D. Pharmaceutical preparations can contain as much as 50,000 IU Vitamin D₂ per capsule / tablet.

Food	Vitamin D (IU ^a /100g)
Animal Products	
<u>Milk</u>	
Cow	0.3-54 ^b
Human	0-10
<u>Dairy Products</u>	
Butter	35
Cheese	12
Cream	50
Eggs	28
<u>Fish Products</u>	
Cod	85
Cod liver oil	10000
Herring	330
Herring liver oil	140,000
Mackerel	120
Salmon	220-440
Sardines	1500
Shrimp	150
^a 1 IU = 0.025mg of Vitamin D ₂ or Vitamin D ₃	
^b US regulations specify that milk be fortified with 400IU of Vitamin D ₃ per quart (about 37IU/100ml)	

Vitamin D toxicity

- Vitamin D intoxication is one of the rarest medical conditions that may be caused either by intentional or inadvertent exposure to excessively high amounts of Vitamin D. Studies have shown that adults can take up to 10,000 IU of Vitamin D a day for at least five months without altering their serum calcium.
- Vitamin D toxicity may cause hypercalcemia, soft tissue calcification etc. Vitamin D intoxication can contribute to increased risk of death.

Fortification levels

- In USA, Fluid milk, when fortified must be declared on the product label. In fortified milk, vitamin A (Retinol Palmitate) shall be present not less than 2000 IU/qt. & Vitamin D₂ (Ergocalciferol) not less than 400 IU/qt within limits of Good Manufacturing vitamin practices. Vitamin A above 6000 IU per quart & vitamin D above 800 IU per quart in Fluid milk is considered harmful.

Safety of fortified foods

Experiences in countries that are already fortifying show that fortified food is completely safe for consumers. The benefits are enormous. The amount of vitamins and minerals added to a specific food is usually set at individuals daily requirements. It is usually less than one third of the total RDAI. Fortification is strictly monitored so that there is no excessive intake of a specific vitamin or mineral. Fortification has negligible impact on the shelf life of the product. Vitamins and minerals have a shelf life of their own although they do become less active over time.

International regulation for fortification

There are no international regulations for food fortification. Codex Alimentarius have issued guidelines for fortification. Countries where a micronutrient deficiency has been identified, vitamins and minerals to be added to overcome this deficiency may be added to foods that are widely consumed. Some countries in Africa apply mandatory fortification to certain basic foodstuffs specifications for which laid down by the Department of Health. Other countries in Africa have developed guidelines for adding vitamins and minerals to foods. Where there are no guidelines, countries consider Codex Alimentarius guidelines as a reference.

Conclusions

Vitamin D deficiency and insufficiency is seen in every country in the world. Lack of awareness of the importance of this deficiency is crucial in individual and public health. Only fish, cod liver oil and mushrooms exposed to sunlight or ultraviolet radiation are the only natural sources. Excess sun exposure is related to skin cancers. Lifestyle changes reduce outdoor exposure for children and many other age groups. The need for fortifying basic foods with Vitamin D is now ever more important. Very few foods are fortified with Vitamin D. Even natural foods provide only a small portion to satisfy either a child's or adults Vitamin D requirement.

In 2008, the American Academy of Pediatrics increased daily supplements recommendation from 200 to 400 IU for infants. For elderly adults , it is 1000 IU/ day. In India, regular daily allowance for Indians as recommended by ICMR and NIN for Vitamin D is 400 IU (10 mcg). Precautions regarding overexposure to sun is justified but moderate sun exposure is especially important for older adults.

All countries in Europe and globally should mandate fortification of milk (including milk formulas, powders and evaporated milk), soft milk products (yoghurts, cheese and others) for prevention of deficiency of Vitamin D, including in sunny countries. International agencies such as WHO, UNICEF and other major donors should promote fortification

India as the largest producer and consumer of milk can not shy away from providing fortified milk to the consumers. Govt. of Rajasthan & Government of Maharashtra already has taken the initiative to supply fortified milk through milk cooperative societies. Regulation on milk and milk products of FSSR, 2011 is presently under review. Also, FSSAI is in the process of harmonization with Codex Alimentarius Commission.

THANK YOU

