

Certain Points Bearing Upon the Desirability of Enrichment of  
Evaporated Milk with Vitamin D

1. Desirability of Additional Vitamin D in the Human Diet

It is now generally recognized that the standard diet of the American public, consisting to a considerable extent of cereal grains, meat, carbohydrates, and fat, is insufficiently provided with calcium to meet the general requirements. Frequent reliance to effect this increase is now placed upon milk and its various products other than butter. Additional reliance is placed upon vegetables. Both of these can be accepted as improving the calcium intake very materially. But in practice it is evident that the consumption of a diet thus enriched will not meet the requirements for children nor for nursing mothers. This is evidenced by the fact that in both of these there result disturbances caused by impoverishment of the skeleton in calcium salts. In children it manifests itself by the incidence of rickets, as becomes apparent by bowing of the legs, contracted chests and pelvis, deformed heads and delayed eruption of the teeth. In nursing mothers the deranged calcium metabolism manifests itself primarily in the loosening and loss of teeth, with or without the inception of caries. In severe cases there may occur a condition known as osteomalacia in which there is prevalent a decreased strength of the bones, resulting in a tendency to fractures.

The consumption of milk in large quantities, even breast milk as a matter of fact - rich though it is in calcium, ordinarily does not meet the requirements of the infant for normal calcium metabolism. It is generally conceded that breast milk is some-

what superior to cows milk, but rickets is produced by both. The incidence of rickets, of course, varies primarily because of different habits of life, resulting in different direct exposure to sunlight or exposure of the nursing mother. The primary deficiency in milk under these circumstances is vitamin D. When this is supplied in sufficient amounts, whether the diet is high or low in calcium, the situation is much improved or completely corrected. On a very low calcium diet vitamin D makes it possible for whatever calcium is present to be used with the greatest efficiency and conservation. When the diet is excessively high in calcium, which moreover does not frequently occur yet must be considered, vitamin D likewise makes the organism use this calcium to best advantage.

It is possible of course that vitamin D may be provided in some other means than through the diet. It is, however, a notorious fact that people under the stress and strain of modern conditions of life will rarely consult a physician for impending difficulties even when realized, and they will rarely adopt a physiological treatment though it may be done with very little inconvenience, until distress is present or exceedingly threatening. Recommendations regarding treatment with different light sources or exposure to sunshine will usually not be complied with unless it falls in line with ordinary habits of living, may they be in connection with play or work.

Introduction of vitamin D in the diet, provided it is done scientifically, provides a means of automatically giving the public what it needs with little or no expense and without effort.

## 2. Milk the Most Desirable Vehicle for Vitamin D Introduction

Milk appears the most desirable to effect this general introduction of vitamin D into the human diet. It is already being widely acclaimed as a health food, and the laborer as well as the artisan and professional man is beginning to consume more and more milk in order to benefit through its health promoting properties. Considering milk as a natural food, it appears exceedingly unfortunate that it should not contain the requisite amount of vitamin D. The incorporation of vitamin D by manufacturing processes supplies the most prominent deficiency of milk and makes it serve its place as an almost indispensable food in the human dietary to better advantage.

It accordingly appears that when milk is supplemented with vitamin D it will gain in reputation thereby, and people consuming more of it will benefit by the intake of the other beneficial constituents of milk such as its excellent protein, its lactose content, and its mineral salts.

## 3. Methods for Introducing Vitamin D into Milk

The research activities of various laboratories in this country, as well as abroad, have revealed that there are available four general methods for incorporating vitamin D into milk. These can be outlined as follows:

- a. The use of a cod liver oil concentrate.
- b. The feeding of irradiated yeast or irradiated ergosterol to the dairy cow.
- c. The direct irradiation of milk.
- d. The direct addition of irradiated ergosterol to milk.

In all the above cases where reference is made to an irradiated product it is assumed that the irradiation was carried out by

treating the product with ultra violet rays such as are generated by the quartz mercury vapor arc or a carbon arc producing radiations of the desired character.

#### 4. The Relative Merits of the Different Methods of Enriching Milk in Vitamin D

The use of a cod liver oil concentrate for the enrichment of milk in vitamin D represents a process which must be most carefully controlled. The concentrate, in the first place, is obtained from cod liver oil - which even from the same source is variable in composition. When obtained from different sources, as the market permits and as the fishing industry and fishing activity vary from year to year, the crude product is bound to change accordingly. The processes of manufacture of the concentrate from the raw oil are controlled with difficulty. The concentrate as finally obtained is nevertheless a product comparatively dilute in vitamin D. It carries many substances which have no physiological merit and which may be actually detrimental. In some cases they carry a decided flavor which is liable to be carried over into the milk enriched. In common with other methods designed to effect enrichment by the incorporation of a rich source of vitamin D, the process as applied to milk directly must be carefully controlled. The standardized concentrate must be used in the desired amount and as such must be emulsified with the milk so that it will be uniformly distributed in the different containers. The use of this concentrate entails the addition of a foreign substance to milk to a considerable extent, which may or may not be an objection.

Method "b" depending upon the direct enrichment of milk by a feeding process introduces vitamin D into the milk by a physiological

reaction. To that extent it may be said to be under physiological control and having passed the selective action of the mammary gland, as well as other tissues of the body, it may thereby constitute a source of vitamin D less inimical, if such is possible, to human welfare. The use of this method carries the necessity of the feeding of the requisite amount of a yeast standardized for its vitamin D content in amounts adjusted to the milk production. This process is valuable only as the execution of it is controlled. If the standardized yeast is not up to potency, or if the dairyman does not feed it in the required amounts, the product will likewise suffer in quality.

In method "c" there is imposed a definite limitation upon the activity which can be induced. This is due to the fact that with excessive treatment, or rather in the last stages of effecting complete activation of the milk, there is produced a change in the fat and in the proteins which results in impaired palatability. The process is therefore limited in use in that the activity induced can be brought up only to a certain point. This is definitely much lower than in the case of method "b" and probably lower than that usually recommended in method "a". However, it has the advantage of decreased cost. The only cost involved is the use of the electric current and the amortization of the equipment, which in the case of continuous use over long periods of time should not be prohibitive.

Method "d" has a distinct advantage over the other methods in respect to flexibility. The irradiated ergosterol can be introduced into milk in practically any amounts which might be desired. It carries no foreign substance inasmuch as ergosterol

can be obtained in a practically pure condition. The amount of substance added to milk is exceedingly small - consisting only of from 40 to 160 thousandths of a milligram per quart of milk. When it is remembered that a milligram is only  $1/28,000$  of an ounce, the minuteness of this dosage can be readily appreciated. The use of this method has a further advantage from the standpoint of factory operation in that with a suitable supply of irradiated ergosterol available almost unlimited quantities of milk can be treated in a very short period of time. Such enrichment of milk is not possible with direct irradiation nor with the feeding of irradiated yeast; it can only be compared with the use of a cod liver oil concentrate. The use of irradiated ergosterol does not entail the difficulties inherent in the variability in raw materials as encountered in the use of a cod liver oil concentrate. Ergosterol is a definite chemical substance which can be obtained in a high degree of purity and can be irradiated to a constancy in potency with little difficulty. From the standpoint of factory operation and control, it appears that the use of irradiated ergosterol would be most advantageous.

##### 5. The Position of the Foundation

The use of any source of vitamin D for any enrichment of a food product in final analysis requires control by biological test. In this respect the Foundation is in an especially fortunate position. The Foundation is equipped with a laboratory which has had experience in vitamin D testing from the very beginning of knowledge relating to this dietary constituent. It, as a matter of fact, formulated the present unit for vitamin D which is used so extensively in the United States. It also has refined the methods

for testing and has correlated various processes as they have been accepted by the scientific professions. Since the formulation of the standards and methods now in use it has had many years experience in the practical testing of the products of its licensees. In any plan of operation it is required by the Foundation that the licensee shall make available directly or as the products may be obtained on the market, samples for testing purposes. The Foundation, furthermore, has taken the precaution of licensing producers of irradiated ergosterol, holding them up to certain standard requirements. By having the producers of irradiated ergosterol under license, as well as having the user of this ergosterol under license, allows the Foundation to make a suitable check-up in a gross way to determine if the products manufactured by the licensee bear the proper relation in total amount to the amount of vitamin D purchased. This, therefore, offers a possibility for dual control.

For laboratory control purposes there are two methods available. These methods consist of what is known respectively as the short time and the long time tests. The short time test requires 10 days for execution, provided that suitably prepared animals are available. The animals are prepared by making them standard rachitic animals. This is done by feeding them a rachitogenic ration for a suitable period of time. The unknown is then introduced into the ration and the amount of healing resulting in the period of 10 days feeding is then taken indicative of the potency of the unknown in vitamin D. In the long time test rickets is prevented in normal animals by feeding them the product from the beginning to the end of the experiment. The prevention or absence of prevention with variable amounts of the unknown addition is taken indicative of the potency.

This latter method requires 5 weeks for actual feeding and at least an additional week for analyses of the ash content of the bones. In each method at least 6 animals are required for the test if the potency can be reasonably well foretold. If the test is too strong or entirely negative it must be repeated with additional groups of 6 until the proper reaction is secured. This means that the expense of testing is variable. It may be that entailed by the mere feeding of 6 animals in a group for 10 days or 5 weeks respectively, or it may be that entailed by successive repetitions with such groups. It is evident that the simplest test cannot be executed for any sum less than \$25; as in most cases the test requires repetition, the final cost can well be taken to be \$75 and in many cases over \$100.

#### 6. Method of Adding Ergosterol

The ergosterol must be added in solution. The solvent had preferably be an oil. This oil may be an oil foreign to fat such as peanut oil, corn oil, cottenseed oil, or sesame oil - provided that these oils have been suitably treated so as not to affect palatability. In case the use of such oils should be questioned, butter oil may be used as a solvent instead. This may be emulsified with a small quantity of milk, and this in turn introduced into larger quantities.

#### 7. Toxicity of Excessive Amounts of Vitamin D

When it was shown some years ago by Pfannstiehl that an excess of certain vitamins, specifically vitamin D, could be responsible for an intoxication, considerable apprehension was aroused regarding the commercial use of vitamin D in food enrichment. This apprehension appears to have been ill founded.



Although irradiated ergosterol has now been on the market for some years in very concentrated form and has been used extensively by the medical profession, there still has to appear a single article in the medical press reporting an intoxication. Experiments with laboratory animals have revealed that a toxic dose represents a therapeutic dose multiplied many thousand times, and that such toxic dose must be taken over a considerable period of time before untoward reactions become manifest. It, of course, is possible that there may be some individuals who may have a higher susceptibility or by virtue of an abnormality have a greater sensitivity to perversion. But the very fact that the medical literature fails to report such a condition indicates that it must be very rare indeed. When it is considered that in food enrichment the addition of vitamin D will be very small and that, as a matter of fact, it will be prophylactic rather than therapeutic, it becomes evident that there is no danger involved.

#### 5. Proper Labeling of Enriched Food Products

There appears no objection to the labeling of foods which have been enriched with vitamin D to the effect that the enrichment is of a certain quality or degree. For instance, it may be suggested that evaporated milk thus enriched should be labeled, "Evaporated milk with Viosterol. X units per pound." It appears that labeling of this character should be no more detrimental to the trade, and as a matter of fact should be of distinct advantage to the consumer, just as the labeling of milk as "evaporated" puts that milk in a particular classification.

### 9. The Amount of Vitamin D to be Added

It appears to me that outside of the statement that the amount of vitamin D is to represent a prophylactic rather than a therapeutic dose, this point should not be brought up for argument. This will leave the Foundation and the licensee perfectly free to act. The question should, however, be brought up with regard to whether or not the label should express the fact that the milk has been enriched.

### 10. Does Fortification with Vitamin D Pave the Way for Future Fortification with other Materials?

It may well be said that if a program of fortification with vitamin D is once started, there will be a demand for fortification with other constituents and the public will thereby become confused and the market for processed milk will become demoralized. This question may be said to provide its own answer. There appears to be no necessity for dealing in the theoretical. If milk requires other supplementations to the same degree as it requires addition of vitamin D, such no doubt will be entertained by the industry and will be welcomed by the consumer. At present it is not evident what these fortifications might be.

### 11. Other Possible Criticisms of the Project

To the minds of those who have been familiar with the general tendency of dietary improvement there seems no lack of justification for the improvement of milk in this manner, and precedent for it seems to be already provided. There, for example, is at present no criticism of pasteurization of milk which is able to stand cross examination. There is, as a matter of fact, no criticism of evaporation, or even of the process of evaporation

combined with the addition of sugar. In each case the product is sold as a special product and is well recognized in the trade as such. In some cases, as for instance in evaporated milk, it is well recognized that evaporated milk due to its heat treatment and consistency has certain distinct advantages over raw milk for infant feeding. It, consequently, does not appear evident that any just criticism may be leveled against the present project provided in the first place that the product is suitably labeled, and that in the second place there is exercised suitable control over the qualitative and quantitative modifications. In the initial stages it is to be expected that the Foundation will assume the responsibility for control as far as the industry is able to meet the requirements. Ultimately it is highly to be desired that the state and federal laboratories will take over the responsibilities in this field.