

VITAMIN D, VITAMIN OR HORMONE? LA VITAMINE D, VITAMINE OU HORMONE ?

Vitamin D recommendations, fortification in France, and communication

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Abstract – The vitamin D has recently been the subject of many researches, demonstrating new effects, reinforcing the interest for this molecule. The interest to develop products fortified with vitamin D is thus very important. Regarding references values, it is necessary to distinguish the RDAs (Recommended Daily Allowances), single value set up at 5 $\mu\text{g}/\text{d}$ for vitamin D at the European level, in order to be a reference and a labeling value, from the nutritional recommendations. These recommendations are defined by groups of population. The values vary according to the countries and the dates on which they were set, the most recent being usually higher. The vitamin D fortification is less constrained in France today than before 2006. To fortify a food with vitamin D, it is necessary to follow the rules set by the Regulation 1925/2006/EC, and use the formulations authorized, demonstrate the nutritional benefit of the fortification, and ensure that the fortification does not lead to a risk for the health of the consumers. In some countries, the vitamin D fortification has been made mandatory for some foods. In France, several products are fortified with vitamin D, especially dairy products, but also some breakfast cereals and vegetable oils. Finally, the communication that can be made on vitamin D in food or advertising is strictly regulated by the Regulation 1924/2006/EC.

Keywords: Vitamin D / recommendations / regulation / fortification / claims

Résumé – **Vitamine D : recommandations, enrichissement en France, et communication.** La vitamine D a récemment fait l'objet de nombreuses recherches scientifiques démontrant des effets nouveaux, renforçant l'intérêt pour cette vitamine. L'intérêt de développer des produits enrichis en vitamine D est donc important. En termes de valeurs de référence, il faut différencier les AJR (Apports Journaliers Recommandés), valeur unique définie à 5 $\mu\text{g}/\text{j}$ pour la vitamine D au niveau européen pour servir de référence et de valeur d'étiquetage, des recommandations nutritionnelles. Ces dernières sont définies par groupe de population. Les valeurs sont variables en fonction des pays et des dates auxquelles elles ont été fixées, les valeurs les plus récentes étant en général plus élevées. L'enrichissement en vitamine D est moins encadré en France aujourd'hui qu'avant 2006. Pour enrichir une denrée alimentaire en vitamine D, il faut aujourd'hui se conformer aux règles édictées par le règlement 1925/2006 /CE, en utilisant les formes autorisées par ce règlement, faisant la preuve de son intérêt nutritionnel, et enfin, dans l'attente des limites maximales qui devraient être fixées, s'assurant que l'enrichissement ne fait pas courir de risque de surconsommation aux consommateurs. Pour la vitamine D, la limite maximale de sécurité est assez élevée, et a été augmentée récemment. Dans certains pays, l'enrichissement en vitamine D a été rendu obligatoire pour certains. En France, de nombreux produits sont enrichis en vitamine D, en particulier des produits laitiers, mais aussi certaines céréales de petit-déjeuner ou huiles végétales. Enfin, la communication qui peut être faite sur la vitamine D sur les denrées alimentaires ou sur la publicité, est strictement encadrée par le Règlement européen 1924/2006/CE.

Mots clés : Vitamine D / recommandations / réglementation / enrichissement / allégations

1 Introduction

The vitamin D has recently been the subject of many researches, demonstrating new effects, reinforcing the interest for this molecule. The interest to develop products fortified with vitamin D is thus very important.

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2 Recommendations

From a regulatory point of view, the only reference value for vitamin D in EU is the RDA (Recommended Daily Allowance), set up at 5 $\mu\text{g}/\text{d}$ in the Directive 90/496/EEC in 1990. The Regulation 1169/2011/EC (INCO), which shall apply from 13 December 2014, uses the same value, with the new name of "NRV" (Nutrient Reference Values).

Table 1. Nutritional recommendations for vitamin D in several countries.

Countries	Children and teenagers				Adults and elderly		Women	
	< 1 years old	1–3 years old	3–13 years old	13–19 years old	> 51 years old	> 65 years old	Pregnant	Lactating
Angleterre (1998) ¹	8.5	7	–	–	–	–	10	10
France (ANC 2001) ²	–	10	5	5	5	5	10–15	10
OMS (2004) ³	5	5	5	5	5	10	15	5
USA/Canada (IOM 2010) ⁴	15	15	15	15	15	15	20	15
Allemagne (GNS 2012) ⁵	10	20	20	20	20	20	20	20
Nordics (NNR 2013) ⁶	–	10	10	10	10	10	20	10

¹ = Department of Health, 1998; ² = ANC, 2001; ³ = OMS, 2004; ⁴ = Institute of Medicine, 2010; ⁵ = New Reference Values, 2012; ⁶ = <http://www.norden.org/en/news-and-events/news/new-nordic-nutrition-recommendations-focus-on-quality-and-the-whole-diet> (values in µg/d).

Table 2. Authorizations for vitamin D fortification in France before 2006.

Food	AFSSA Opinion	Maximal Level	Arrêté
Milk	2001	1 µg/100 ml	<i>Arrêté du 11 octobre 2001 relatif à l'emploi de vitamine D dans le lait et les produits laitiers frais</i>
Dairy product	2001-SA-0094	1.25 µg/100 g	
Vegetable oils	2002 2001-SA-0030	5 µg/100 g	<i>Arrêté du 8 octobre 2004 relatif à l'emploi de vitamine D3 dans les huiles végétales</i>

Nevertheless, there are many other nutritional recommendations for vitamin D, usually defined by groups of population, specific from one country to another (see Tab. 1).

Generally, the more recent the values are set up, the higher they are: the lower values are defined for UK (in 1998) or France (in 2001), the higher for Germany (in 2012).

When the countries revise the recommendations for vitamin D, they usually increase it, acknowledging the new data available on this vitamin.

For instance:

- the recommendations for vitamin D in the USA have been tripled in 2010;
- end of 2013, the Nordic Countries have increased their recommendations for vitamin D from 2004, increasing them from 7.5 µg/d to 10 µg/d for children and adults, and to 20 µg/j for elderly.

Thus the question is really to know if the French ANR (*Apports Nutritionnels Recommandés*) ought not to be increased too.

3 Fortification

Until 2006, in France, the food fortification was strictly regulated. In order to fortify a food with a vitamin or mineral, it was necessary to submit a file to the French Agency for Food Security (AFSSA), demonstrating the benefits and safety of the fortification. The file had to be made for specific products.

When the opinion of the Agency was positive, a regulatory text was published and gave the authorization of fortify the food.

For instance, authorization had been given to fortify vegetable oils with vitamin D (concentration of 10 µg/100 g), milk and dairy products (concentration of 1 and 1.25 µg/100 g) (see Tab. 2).

Since 2006, the regulatory frame is different: the regulation 1925/2006/EC introduced new rules, common all around the European Union.

This regulation allows the fortification of foods with vitamins and minerals without prior specific authorization, as long as the rules that have been set up are respected:

3.1 Restrictions

Some products are not allowed to be fortified: unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry and fish, and beverages containing more than 1.2% by volume of alcohol.

3.2 Conditions for the addition of vitamins and minerals

- *Minimum fortification*: the addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC.

Table 3. Examples of mandatory food fortifications in vitamin D.

Country	Food	Status	Level of fortification
Canada	Milks	Mandatory	1.75 µg/100 ml
	Vegetable spreads	Mandatory	13.25 µg/100 g
Australia	Vegetable spreads	Mandatory	5.5 µg/100 g
Finland	Milks and yoghurts	Optional, but widespread	0.5 µg/100 g
	Vegetable spreads		10 µg/100 g
USA	Fortified milks	Mandatory	1.05 µg/100 g
	Other milks	Optional, but widespread	1.05 µg/100 g
	Breakfast cereals		3.5 µg/100 g

For vitamin D, this implies that a fortified food should at least contain 15% of the RDAs, i.e. 0.75 µg/100 g of vitamin D.

- **Maximum fortification:** the regulation 1925 /2006 states that “When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts that shall be set in accordance with the procedure referred to in Article 14(2). The Commission may, to this end, submit proposals for the maximum amounts by 19 January 2009”.

Nevertheless, as these maximum amounts have still not been set, it is for the moment the responsibility of the operator to define what level of fortification is safe for consumers.

A solution is for instance to conduct studies simulating the effect of the fortification of a food on the consumption of the vitamin or mineral for the population. The simulating vitamin intake can then be compared with the upper safe level for the vitamin or mineral, set up by EFSA. This can be done by using studies such as INCA 2 for France. For vitamin D the tolerable upper intake level was set by EFSA in 2012 at 100 µg/day for adults including pregnant and lactating women, and adolescents for ages 11–17 years, at 50 µg/day for children aged 1–10 years, and at 25 µg/day for infants.

3.3 Requirements

- **Form of fortification:** only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II of the regulation 1925/2006, may be added to foods: vitamin D is listed in the Annex I, and may be added to foods as cholecalciferol or ergocalciferol.
- **Justification for the fortification:** vitamins and minerals may be added to foods, whether or not they are usually contained therein, in order to take into account, in particular:
 - a. a deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients; or
 - b. the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits; or

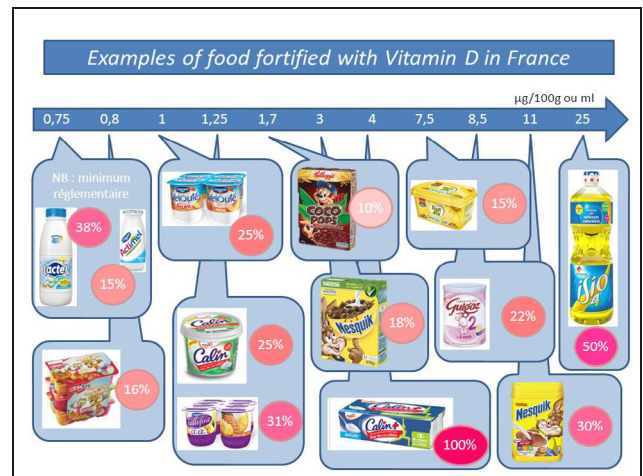


Fig. 1. Examples of food fortified with vitamin D in France.

- c. evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

For vitamin D, it is quite simple to demonstrate that a food fortification answers one of these issues, as, in France:

- 80% of the French population presents a deficiency in vitamin D (Castetbon, 2009),
- and the average intake of vitamin D in the French population is largely below the ANC: 1.9 µg/d for children aged 3–19 years, and 2.6 µg/d for adults (Afssa, 2006–2007).

In some countries, the vitamin D fortification has been made mandatory for some foods: for instance in Canada or Australia, all vegetable spreads have to be fortified with vitamin D. Milk is sometimes also fortified. Nevertheless, the concentrations of these fortifications vary a lot from one country to another (see Tab. 3).

In France, several products are fortified with vitamin D, especially dairy products, but also some breakfast cereals and vegetable oils (see Fig. 1)

The fortification targets different populations:

- many products are for children (breakfast cereals, chocolate powder, dairy products),
- some others for the whole family (vegetable oil and fat, milk),
- and finally some for women and elderly (dairy products).

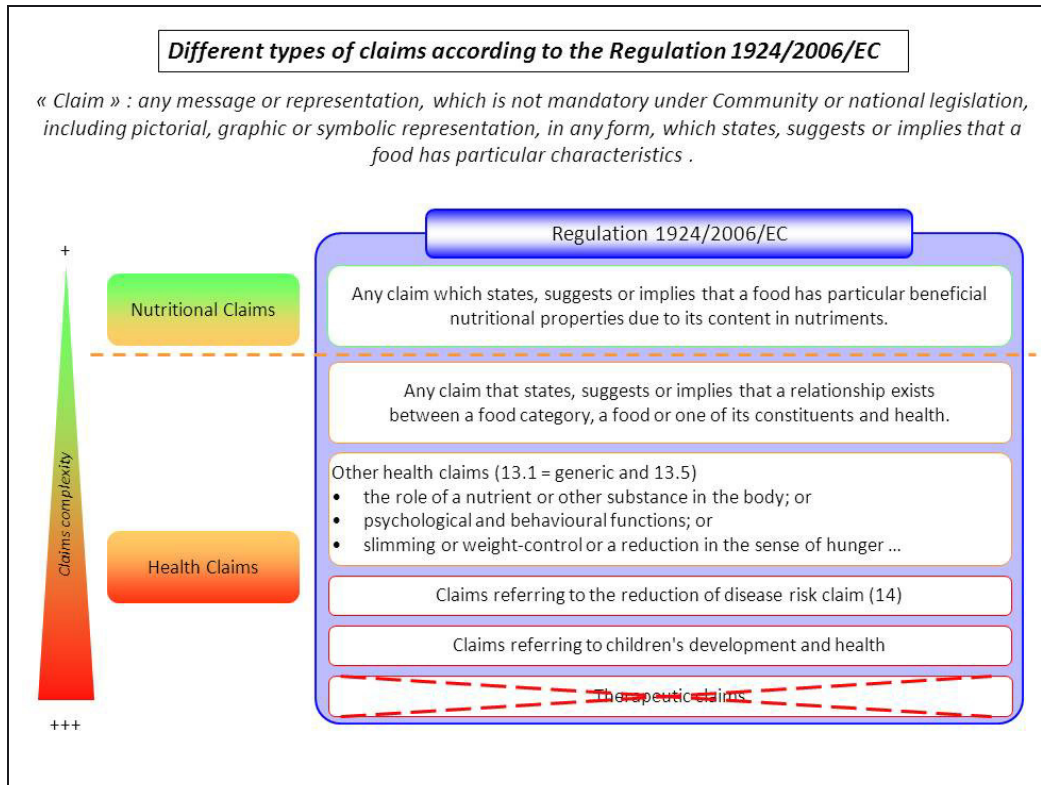


Fig. 2. Different types of claims according to regulation 1924/2006/EC.

The concentrations of vitamin D vary a lot from one product to another, from 0.75 µg/100 g (minimum as set by the regulation) to 25 µg/100 g, which represents, per portion, a dose of 10 to 100% of the RDAs for vitamin D.

4 Communication

In Europe, the communication made on vitamin D in foods is strictly regulated by the regulation 1924/2006/EC.

This regulation applies since 2007, and concerns every commercial communications made on foods, whether in the labeling, presentation or advertising.

It defines the different types of claims that can be used: nutritional claims, generic health claims, health claims related to the development of children or to the reduction of disease risk (see Fig. 2).

It sets up the rules to communicate nutritional benefits to consumers:

- The only claims that can be used (either nutritional claims or health claims) are the claims that have been specifically authorized:
 - For nutritional claims (such as “source of vitamin D”) a list has been directly authorized in the regulation, including about 25 claims.
 - For health claims, dossiers supporting the claims have been completed by industrial, and have been evaluated by EFSA. The claims which had received a positive opinion from EFSA are then authorized by a regulation.

- For each claim, specific conditions of use are defined, and must be followed.
- Finally, the regulation should define the “nutritional profiles”, *i.e.* the conditions that a food product must meet in order to “deserve” to use claim in terms of nutritional content. This should have been done before January 2008.

For vitamin D, several claims have been accepted:

4.1 Nutritional claims

- “Source of vitamin D”: in order to bear this claim, the product must contains at least a significant amount as defined in the Annex to Directive 90/496/EEC, *i.e.* 15% of the RDA, 0.75 µg of vitamin D per 100 g or 100 ml.
- “High in vitamin D”: in order to bear this claim, the product must contains at least twice the value of “source of”, *i.e.* 30% of the RDA, 1.5 µg of vitamin D per 100 g or 100 ml.

4.2 Health claims

- *Generic claims*: Seven generic claims have been accepted for vitamin D. They are related to five topics: absorption and utilization of calcium or phosphorus, maintenance of bones and teeth, muscular function, immune function and inflammation, cell division (see Tab. 4)
Moreover two claims on vitamin D have been refused, because EFSA estimated that, based on the available data,

Table 4. Authorized health claims for vitamin D in Europe.

Health benefit	Claim	Conditions of use
Absorption and utilization of calcium or phosphorus	Vitamin D contributes to normal absorption/utilisation of calcium and phosphorus Vitamin D contributes to normal blood calcium levels	
Maintenance of bones and teeth	Vitamin D contributes to the maintenance of normal bones Vitamin D contributes to the maintenance of normal teeth	Source of vitamin D
Muscular function	Vitamin D contributes to the maintenance of normal muscle function	
Immune function and inflammation	Vitamin D contributes to the normal function of the immune system	
Cell division	Vitamin D has a role in the process of cell division	

a cause and effect relationship has not been established between the dietary intake of vitamin D and the claimed effect. The proposed claims were “vitamin D and normal thyroid function”, and “vitamin D and normal cardiac function”.

- *Health claims referring to children’s development and health*: two claims have been accepted, with the same condition of use (source of vitamin). These two claims are:
 - Vitamin D is needed for normal growth and development of bone in children.
 - Calcium and vitamin D are needed for normal growth and development of bone in children.
- *Claims referring to the reduction of disease risk*: for the time being, no claim referring to the reduction of disease risk has been accepted for vitamin D. Nevertheless, a claim has received a positive opinion of EFSA (2011): on the basis of the data presented, the panel has concluded that a cause and effect relationship has been established between the intake of vitamin D and a reduction in the risk of falling. In order to obtain the claimed effect, 800 I.U. (20 µg) of vitamin D from all sources should be consumed daily. The target population is men and women 60 years of age and older. This claim should be authorized soon.

5 Conclusion

- The nutritional recommendations in vitamin D are very different from one country to another, and seem especially low in France.
- The food fortification with vitamin D is allowed by the regulation, but the levels of fortification are the choice of the food operator.
- In France the main products fortified with vitamin D are dairy products, but also some breakfast cereals and

vegetable oils, targeting children, women and elderly, or, for some products, the whole family. The level of fortification varies a lot from one product to another.

- In terms of communication, a limited number of claims is allowed, nutritional claims such as “source or high in vitamin D”, or health claims on topics such as bone and teeth health, cell division, immune system, muscular function.

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