Vitamin D Matters:
Where Does the Bakery Industry Fit?

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Vitamin D Fortification: A United States' Perspective

Vitamin D … it's often called the "nutrient of the era." Although well recognized for its role in growth and bone health, in recent decades this fat-soluble vitamin has received little attention. Fortification of milk in the 1930s in the United States essentially eliminated rickets, caused by a vitamin D deficiency. Yet emerging scientific research indicates that vitamin D may have more far-reaching health benefits – ironically, at a time when vitamin D status and the re-emergence of rickets are concerns once again.

While the human body makes vitamin D through exposure to sunlight, it's also needed in the diet. Among the many reasons: many people don't get enough sunlight exposure to make what the body requires. Studies show, they may not consume minimum levels of vitamin D for bone health either. Beyond that, emerging science suggests that optimal intake for health may exceed current vitamin D advice for adequacy. Higher vitamin D intake may help protect against many health problems, such as diabetes, heart disease, some cancers, and autoimmune diseases, including multiple sclerosis and rheumatoid arthritis.

Fortification is an appropriate strategy for addressing public health concerns about the vitamin D shortfall … when added to the right foods, in the right amounts, for the right target population.

Can the bakery industry partner in addressing vitamin D inadequacy? United States (U.S.) Food and Drug Administration (FDA) regulations allow discretionary vitamin D fortification of bakery foods. Yet with unknowns about health benefits, optimal intake, and dietary guidance for vitamin D, the bakery industry should proceed cautiously until more science-based vitamin D guidance is available. Among the issues:

- ***Emerging science, pending recommendations*.** Except for bone health, scientific evidence on the health benefits of vitamin D is inconclusive. Currently the Dietary Reference Intakes, established by American and Canadian scientists, provide only provide minimal, not optimal, advice for vitamin D. Updated vitamin D and calcium recommendations are scheduled for release from the Institute of Medicine (IOM) in June, 2010. Although the U.S. Dietary Guidance Advisory Committee recognizes vitamin D as a shortfall nutrient, new IOM recommendations may not be released in time for full consideration in the *Dietary Guidelines for Americans, 2010.*

- ***Right bakery products for the targeted population.*** The bakery industry needs to determine whether baked foods are appropriate for vitamin D fortification -- and if so, which products are consumed by those at risk for vitamin D deficiency. It's important to note that for bone health, vitamin D works with calcium. While milk naturally contains significant amounts of other bone-building nutrients (calcium, phosphorus, magnesium), bakery goods do not. That said, milk is not the beverage of choice for all consumers. Except for fortified breakfast cereals in the U.S., grain products are not readily recognized by consumers as sources of vitamin D.

- ***Form of vitamin D for fortification.*** Current U.S. labeling laws treat vitamins D_2 and D_3 equivalently and interchangeably. As an additive, vitamin D_2 comes from plant-based sources; vitamin D_3, from animal-based sources. Both forms are approved for bakery products. Scientific evidence on the bioavailability of different forms vitamin D is not conclusive. Since vitamin D and calcium work as partners in bone health, fortifying with appropriate levels of calcium should be considered when fortifying with vitamin D.

- ***Vitamin D fortification levels.*** The U.S. FDA has set the fortification level for grain products, including bakery products, at ≤90 IU of vitamin D per 100-gram serving from any source. For bread or a bakery roll, that is a *maximum* fortification level of 45 IU vitamin D per 50-gram bread slice *or* roll. *(The maximum level for other bakery products, based on reference amount for labeling, is noted in Table 6.)*

  Among other fortification considerations: 1) In the future, the bakery industry may choose to establish a standard level for vitamin D in specific bakery products (as done for fortified milk) to help consumers make decisions about *v*itamin D-fortified foods. 2) Adding vitamin D to flour allows *co*ntrol over fortification levels, noting varying product formulations among bakery products. *3)* Vitamin D fortification in the total diet, including bakery products, should be considered to avoid adverse effects of excessive vitamin D intake.

- ***U.S. labeling issues****.* If a product is vitamin D fortified, vitamin D must appear in the ingredient list and in the Nutrition Facts panel, shown as noted in food labeling regulations. If one label serving has at least 10% Daily Value (DV), or 40 IU, the label also can carry a nutrient content claim as a "good source" of vitamin D. The product name also must reflect the appropriate nutrient content claim and the appropriate standardized term for the product, such as "Vitamin D Fortified Enriched Bread,"

  Also of note: *1*) The current allowable level of vitamin D in bakery products is not high enough to qualify a vitamin D-fortified bakery product as an "excellent source" of vitamin D. A product needs to have at least 20% DV of a given nutrient to be an "excellent source." For vitamin D that would be 80 IU or more vitamin D per label serving. 2) The Daily Values for vitamin D, set by food labeling regulations, differ from the DRIs. Until labeling regulations change, the current DV for vitamin D will remain at 400 IU even if the DRIs for vitamin D change in 2010. 3) Although a health claim linking vitamin D and calcium to bone health has been approved, bakery products cannot be fortified at levels high enough for vitamin D and calcium to make this health claim.

- ***Marketing to consumers.*** An effective, science-based consumer information effort for vitamin D overall and in vitamin D-fortified bakery foods (including label-reading and menu planning skills) will be needed, by the bakery industry in partnership with other nutrition education efforts.

Fortification and labeling regulations in the U.S. differ from those in Canada. For issues related to vitamin D recommendations, fortification, and labeling in Canada, refer to "Vitamin D Fortification: A Canadian Perspective."

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Vitamin D Fortification: A Canadian Perspective

Vitamin D … it's often called the "nutrient of the era." Although well recognized for its role in growth and bone health, in recent decades this fat-soluble vitamin has received little attention. Fortification of any form of milk since the 1970s in Canada essentially eliminated rickets, caused by a vitamin D deficiency. Yet emerging scientific research indicates that vitamin D may have more far-reaching health benefits – ironically, at a time when vitamin D status and the re-emergence of rickets are concerns once again.

While the human body makes vitamin D through exposure to sunlight, it's also needed in the diet. Among the many reasons: many people don't get enough sunlight exposure to make what the body requires, especially due to Canada's northern latitudes. Studies show, they may not consume minimum levels of vitamin D for bone health either. Beyond that, emerging science suggests that optimal intake for health may exceed current vitamin D advice for adequacy. Higher vitamin D intake may help protect against many health problems, such as diabetes, heart disease, some cancers, and autoimmune diseases, including multiple sclerosis and rheumatoid arthritis.

Fortification can be an appropriate strategy for addressing public health concerns about the vitamin D shortfall … when added to the right foods, in the right amounts, for the right target population.

Can the bakery industry partner in addressing vitamin D inadequacy? Canadian regulations allow only limited voluntary vitamin D fortification at this time. Bakery products *are not identified* in Canada's *Food and Drug Regulations* as a category for voluntary fortification. Without regulatory guidance -- and with unknowns about the health benefits, optimal intake, and dietary guidance for vitamin D -- the bakery industry should proceed cautiously. Among the issues:

- ***Emerging science, pending recommendations*.** Except for bone health, scientific evidence on the health benefits of vitamin D is inconclusive. Currently the Dietary Reference Intakes, established by Canadian and American scientists, only provide minimal, not optimal, advice for vitamin D. Updated vitamin D and calcium recommendations will be released from the Institute of Medicine (IOM) in June, 2010. In a 2007 statement Health Canada recognized that significant evidence has emerged since the IOM established recommendations for vitamin D in 1997, and it committed to working closely with the U.S. Department of Health and Human Services to determine how best to update the DRIs for vitamin D.

- ***Need for regulatory support for vitamin D fortification.*** The bakery industry needs to determine whether baked foods are appropriate for vitamin D fortification. If so, it should play an appropriate role in supporting the issuance of Canadian regulations for the vitamin D fortification of bakery foods. Among the considerations for setting fortification levels:
    - Specified levels of fortification should be based on current science-based recommendations for vitamin D, as well as calcium. For bone health, vitamin D and calcium work together. (Currently Canada allows calcium fortification of some flours.) While milk naturally contains significant amounts of other bone-building nutrients (calcium, phosphorus, magnesium), bakery foods do not. That said, milk is not the beverage of choice for all consumers.
    - The bakery industry may choose to establish a standard level (or range) for vitamin D in specific bakery products (as done for fortified milk) to help consumers make decisions about vitamin D-fortified foods.
    - Adding vitamin D to flour allows control over fortification levels, noting variability of vitamin D with product formulations among bakery products.
    - Vitamin D fortification in the total diet, including bakery products, should be considered to avoid adverse effects of excessive vitamin D intake.

  The IOM acknowledges that food fortification in Canada has been tightly regulated, but also notes that the situation is changing. The result may be more options for discretionary fortification in the future.

- ***Form of vitamin D for fortification.*** Current Canadian labeling laws treat vitamins D_2 and D_3 equivalently and interchangeably. As an additive, vitamin D_2 comes from plant-based sources; vitamin D_3, from animal-based sources. Scientific evidence on the bioavailability of different forms vitamin D is not conclusive. Since vitamin D and calcium work as partners in bone health, fortifying with appropriate levels of calcium should be considered when fortifying with vitamin D.

- ***Canadian labeling issues***. Canadian regulations, including labeling and fortification levels, have been established for foods that are vitamin D fortified. Current regulations, however, do not include bakery foods. Unless adequate vitamin D levels were provided by ingredients such as vitamin D-fortified milk or margarine, bakery foods could not carry a nutrient content claim, a nutrient function claim, or health claim related to vitamin D. Labeling regulations in Canada differ from those in the U.S.

- ***Marketing to consumers.*** An effective, science-based consumer information effort for vitamin D overall and in vitamin D-fortified bakery foods (including label-reading and menu planning skills) will be needed if vitamin D fortification in bakery foods is allowed, by the bakery industry in partnership with other nutrition education efforts. Currently grain products are not recognized by consumers as sources of vitamin D.

For issues related to vitamin D recommendations, fortification, and labeling in the United States, refer to "Vitamin D Fortification: United States' Perspective."

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Vitamin D Matters:

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Vitamin D fortification may offer an opportunity for the bakery industry. Options should be weighed in context of the total diet along with science-based knowledge on vitamin D: what's well known about vitamin D's role in health … its sources, including fortified foods … emerging evidence on its health benefits and optimal intake … current intake recommendations, as well as pending updated advice … and current regulations related to vitamin D fortification and labeling.

Vitamin D 101: The Basics

Why is vitamin D a current health concern? What is its role in human health? What foods provide this essential vitamin? How much is enough -- and too much? And what emerging science is shaping our understanding of vitamin D's health benefits?

More than one source...

- *Ultraviolet light.* Nicknamed the "sunshine vitamin," vitamin D's uniqueness lies in the body's ability to synthesize it. When ultraviolet (UV) light from sun penetrates bare skin, 7-dehydrocholesterol (a form of cholesterol) in the body converts to vitamin D_3 (cholecalciferol), which is a biologically inert form of vitamin D.
- *Unfortified foods*. As a fat-soluble nutrient, vitamin D_3 occurs naturally but in limited supply. Only a few foods are good sources: oily fish such as salmon and mackerel, tuna packed in oil, and fish oils. Beef liver, egg yolk, and cheese contain much smaller amounts. (*See Table 1.)* Some mushrooms provide varying amounts of vitamin D_2 (ergocalciferol), another inert form of vitamin D; a plant sterol (ergosterol) converts to vitamin D when exposed to UV light. Vitamin D_2 is also derived from yeast.
- *Fortified foods.* Because foods naturally rich in vitamin D are limited, most vitamin D in the U.S. diet comes from a handful of fortified foods: vitamin D-fortified milk and some other milk products (mostly yogurt and cheese), as well as calcium- and vitamin D-fortified products, such as some fruit juices, juice drinks, soy products, meal replacement bars, infant formula, ready-to-eat cereals, and breads. *(See Table 1.)* Since the 1930s in the United States and since the 1970s in Canada, most milk has been fortified with vitamin D_3 as a way to prevent children from developing rickets, a vitamin D deficiency disease. The amount is standardized in the U.S. to 100 IU per 8-ounce and in Canada as 300 - 400 IU per Reasonable Daily Intake of milk. (Reasonable Daily Intake is defined by regulation as 30 fl. oz., or 852 ml *per day*.) Both forms -- vitamins D_2 and D_3 -- are used in fortification.
- *Dietary supplements.* In varying amounts, dietary supplements are another source, with vitamin D generally provided as cholecaliciferol, or vitamin D_3.

With the growing interest in vitamin D, the U.S. Department of Agriculture's update of its USDA Nutrient Database for Standard Reference, Release 22, now includes vitamin D values for about 3,000 foods. The update, released in October, 2009, includes vitamin D data (as IUs) for 20 species of fish and many vitamin D-fortified foods. As available, values for both vitamins D_2 and D_3 (in micrograms) also were provided. Website: www.ars.usda.gov/nutrientdata.

In Canada vitamin D data is provided in the Canadian Nutrient File, showing micrograms of vitamin D -- both reasonable portions and gram weights -- for about 1850 foods. Website: http://www.hc-sc.gc.ca/fn-an/nutrition/fiche-nutri-data/index-eng.php

Table 1: Food Sources of Vitamin D*

Food	IUs per serving*	Percent DV in the U.S.**
Salmon, sockeye, cooked, dry heat, 3 ounces	794	198
Salmon, pink, canned solids with bone and liquid, 3 ounces	465	116
Tuna fish, light, canned in oil, drained, 3 ounces	229	57
Fluid milk (nonfat, reduced fat, whole), vitamin D-fortified, 8 ounces	115-124	29-31
Orange juice, vitamin-D fortified, 1 cup ***	100 (amount varies)	25 (amount varies)
Yogurt, fortified at 20% DV, 6 ounces ***	80	20
Beef, variety meats, liver, pan fried, cooked, 3 ounces	42	10
Ready-to-eat cereal, vitamin D fortified, 3/4 to 1 1/4 cups	40 to 100	10 to 25
Egg, 1 large (found in yolk)	22	6
Cheese, Swiss, 1 ounce	6	2
Mushrooms, white, raw, 1 cup	5	1

* IUs = International Units
** DV = Daily Value. The DV for vitamin D, used in U.S., is 400 IU for adults and children age 4 and older. The DV in Canada is 5 micrograms (µg), or 200 IU, per day for those ages 2 years and older.

Most data from U.S. Department of Agriculture, Agricultural Research Service. *USDA Nutrient Database for Standard Reference, Release 22*, 2009.

*** Manufacturer's data from Nutrition Facts panels; amount of vitamin D per label serving varies, depending on fortification levels.

From inert to biologically-active form **...**Through hydroxylation, both forms -- vitamins D_2 and vitamin D_3 -- are converted in the liver to calcidiol, or 24(OH)vitamin D, which circulates in the bloodstream. Circulating serum 24(OH) vitamin D is used to measure an individual's vitamin D status; more research is needed to determine the appropriate level for optimum health.

Vitamin D becomes active when it converts from calcidiol to calcitriol (its metabolically active hormonal form) in the kidneys along with other tissues and body cells.

For bone health and beyond **...** Vitamin D works in partnerships with other nutrients and hormones. As calcitriol, vitamin D plays a key role in bone health. It enhances calcium and phosphorus absorption in the gut, keeps calcium and phosphate concentrations at a level needed for normal bone mineralization, and promotes growth and bone remodeling. For children that means proper bone formation; for adults, maintaining bone strength.

As a side note, calcium is absorbed in two ways – one requiring vitamin D, the other, not. When vitamin D intake is insufficient, one mechanism is compromised. To compensate, calcium intake needs to be higher to allow enough calcium absorption from the other mechanism, but how much? Most people do not

consume enough calcium to meet that added demand – another reason to maintain adequate vitamin D status.

A growing, *yet inconclusive*, body of evidence indicates broader roles for vitamin D, which are independent of calcium absorption and of bone health. Research is mostly epidemiological; clinical studies are needed.

- As an important metabolite, calcitriol is a cellular essential. It helps regulate other body functions, including the production, growth, and differentiation of body cells and the normal functioning of the immune system.
- Optimal vitamin D status may offer protection from certain cancers. The links to lower colon cancer risk are strongest, but vitamin D may also help protect against breast and prostate cancers.
- Other studies indicate links between vitamin D status and heart health, blood pressure regulation, diabetes, glucose intolerance, and autoimmune diseases, including multiple sclerosis, rheumatoid arthritis, and Crohn's disease.

How much is enough… With adequate exposure to sunlight, the skin of healthy individuals can manufacture nearly all the vitamin D needed. Yet, due to limited or irregular exposure to sunlight, even for healthy people, vitamin D has been identified as an essential dietary nutrient in the U.S.

Dietary Reference Intakes (DRIs) for vitamin D, were established in 1997. *(See Table 2.)* The DRIs are a comprehensive set of nutrient reference values for healthy populations, set by American and Canadian scientists, with oversight by the Food and Nutrition Board (FNB), Institute of Medicine (IOM), an independent, nongovernmental body in the U.S. DRIs include Adequate Intake Levels (AIs), Recommended Dietary Allowances (RDAs), and Tolerable Upper Intake Levels (ULs).

- AIs for vitamin D are minimum daily amounts needed by healthy people for bone health and calcium metabolism – and assume no sun exposure. Because vitamin D metabolism declines with age, AIs for vitamin D are higher for older adults, with recommendations increasing at age 51 and again at age 71.
- ULs are the maximum daily intake for vitamin D that probably would not cause adverse health effects.
- Due to insufficient scientific evidence, no RDAs for vitamin D were established in 1997. (The RDA is the average daily intake level adequate to meet the nutrient needs of nearly all healthy Americans.) Optimal intake levels for vitamin D have not been determined.

Table 2: How Much Vitamin D Is Currently Advised?

Age and Stage of Life	Adequate Intake (AI)***		Tolerable Upper Intake Level (UL)***	
	Calciferol (vitamin D_3) (mcg)*	IU**	Calciferol (vitamin D_3) (mcg)	IU
1 to 50 years (including pregnancy or lactation for women)	5	200	50	2,000
51 to 70 years	10	400	50	2,000
71 or more years	15	600	50	2,000

* One microgram calciferol (vitamin D_2 or vitamin D_3) equals 40 IU of vitamin D in these recommendations..

** IU = International Units

** The AI is the amount adequate to maintain bone health and normal calcium absorption in healthy people. The UL is the maximum level that probably will not pose a health risk for healthy people.

Source: Food and Nutrition Board, Institute of Medicine, 1997

A growing body of science-based evidence is expanding knowledge about the needs for, and the roles and benefits of, vitamin D. A 2009 research review in the *American Journal of Clinical Nutrition* called for higher DRI levels for vitamin D. Some experts advise a level closer to 1000 IU per day, much higher than current AIs. In its *Guiding Principles for the Discretionary Addition of Nutrients to Foods*, published in 2003, the IOM noted that AI levels in the current DRIs are not high enough for those who do not produce enough in their skin through sun exposure. By May, 2010, updated DRIs for vitamin D, as well as calcium, are expected from the FNB/IOM.

In early 2009 the Dietary Guidelines Advisory Committee (DGAC) in the U.S. acknowledged that IOM's updated vitamin D recommendations should be addressed in the *Dietary Guidelines for Americans, 2010*, scheduled for release by USDA and HHS in fall, 2010. The November 2009 DGAC meeting reported a vitamin D shortfall for adults and children, based on a review of the scientific evidence. and *proposed* that vitamin D *may be identified* as a nutrient of concern for the 2010 guidelines. Since the IOM report will not be released until late spring, 2010, some speculate that there may not be enough time to fully address new vitamin D recommendations within the 2010 Dietary Guidelines. In a 2007 statement Health Canada recognized that significant evidence has emerged since the IOM established recommendations for vitamin D in 1997, and it committed to working closely with the U.S. Department of Health and Human Services to determine how best to update the DRIs for vitamin D.

In 2008 the American Academy of Pediatrics (AAP) established higher recommendations for vitamin D for healthy children and adolescents: 400 IUs daily -- twice the AI level set by the FNB in 1997. The AAP advises a daily vitamin D supplement for those who do not consume 400 IU of vitamin D daily from milk and other food. After reviewing evidence on widespread vitamin D and calcium deficiency throughout the world and the U..S., especially among those ages 50 years and above, the National Osteoporosis Foundation (NOF) updated its vitamin D recommendations in 2008. It advises adults under age 50 to consume 400 to 800 IU vitamin D daily, and adults age 50 and older, 800 – 1,000 IU vitamin D daily. NOF identifies both food and supplement sources. For supplements, it notes that recent studies show that vitamin D_3 and vitamin D_2 are equally good for bone health.

Health Canada (Santé Canada) provides vitamin D recommendations until the DRIs are updated (in 2010):

- To prevent rickets, all breastfed, healthy-term babies should receive a daily vitamin D supplement of 400 IU from birth until the diet (food) can provide 400 IU per day or until breastfed infants are one year of age. Formula-fed infants should consume vitamin D-fortified formula.
- After one year, children should consume 200 IU vitamin daily, which is provided in two cups of milk or vitamin D-fortified soy beverage.
- Canadians over two years of age, including pregnant and lactating women, are urged to consume two cups of milk or vitamin D fortified soy beverage, which will supply 200 IU per day.
- Adults age 50 years and over are advised additionally to take a daily vitamin D supplement of 10 micrograms (400 IUs) since the food pattern in Canada's Food Guide does not provide enough vitamin D to meet the AI established by the IOM.

While some organizations in Canada -- including the Canadian Cancer Society -- have issued increased recommendations for vitamin D, Health Canada believes these recommendations are premature and that more research review is needed on the benefits and safety of higher vitamin D levels before revising its recommendations for Canadians.

To reduce the risk of certain cancers, the Canadian Cancer Society recommends: 1) adults living in Canada should consider taking Vitamin D supplementation of 1,000 IUs daily during the fall and winter, and 2) adults at higher risk (who are older, with dark skin, who don't go outside often, who wear clothing that covers most of their skin) of lower Vitamin D levels should consider taking Vitamin D supplements with 1,000 IU per day all year round.

Often a shortfall … Despite its availability, vitamin D often comes up short. Vitamin D status is determined with biological indicators; since the DRI for vitamin D is an Adequate Intake level, calculating the prevalence of vitamin D inadequacy with this reference value is not possible, notes IOM.

A vitamin D deficiency can lead to health problems, especially related to bone health. Among some groups of children, the incidence of rickets is resurging. With rickets, bones do not mineralize adequately, causing soft bones and skeletal deformities. Among adults, vitamin D deficiency is often undetected for years, even as it leads to osteomalacia, characterized by weakened muscles, weak bones, and perhaps bone pain. In the long run this contributes to osteoporosis later in life. In the U.S. 10 million Americans currently are estimated to have osteoporosis, according the National Osteoporosis Foundation, with 34 million more at risk due to low bone mass. Approximately 1.4 million Canadians are affected by osteoporosis, according to statistics reported by the International Osteoporosis Foundation.

Research also indicates that vitamin D deficiency during pregnancy is linked adversely to infant development.

Vitamin D deficiencies have multiple causes, among them:

- *Low intake of dietary vitamin D over time*. Those who limit or avoid vitamin D-fortified milk due to a milk allergy, lactose intolerance, a vegan diet, cultural food practices, or a preference for other beverages such as soft drinks are often at risk.
- *Limited exposure to direct sunlight.* This often results from indoor life-and work-styles, living at latitudes with less winter sunlight such as the northern U.S. and throughout Canada, being homebound for health reasons, clothing that covers much of the skin, and heavy use of sunscreen. Those with dark skin are also at higher risk; the pigment melanin reduces the skin's ability to produce vitamin D.
- *Aging.* With age, skin does not synthesize vitamin D as efficiently. Kidneys do not convert vitamin D to its active form as efficiently either.
- *Fat malabsorption.* Because vitamin D is fat soluble, fat malabsorption is also linked to health problems such as Crohn's disease, cystic fibrosis, and liver disease. Those who have had part of their upper small intestine surgically removed are also at greater risk. Vitamin D is absorbed in this part of the digestive tract.

Currently there is no consensus on *optimal* vitamin D status. As a result, the number of people who are vitamin-D deficient has not been determined. The USDA Agriculture Research Service estimates that a significant percentage of Americans may consume less dietary vitamin D than considered adequate (AI) in the 1997 DRIs.

Statistics Canada, in partnership with Health Canada and the Public Health Agency of Canada, is conducting the Canadian Health Measure Survey (CHMS), which will provide the first national data on the vitamin D status of Canadians in over 35 years. A full report will be released in 2010. Preliminary data from 5,500 Canadians was released in July, 2009, for use in developing updated IOM recommendations for vitamin D.

Too much of a good thing … While necessary for health, dietary vitamin D in large doses can pose health risks, among the symptoms: constipation, nausea, vomiting, poor appetite, and weight loss. Because of its role in calcium absorption, vitamin D toxicity can also raise blood levels of calcium, causing mental confusion, irregular heart rhythms, or kidney stones. A high intake of vitamin D from supplements would be the likely cause. Excessive exposure to sunlight does not cause vitamin D toxicity.

Vitamin D Fortification: Current Regulations in the United States

Forms of vitamin D for fortification … Two forms of vitamin D are used to fortify foods. As an additive, vitamin D is "generally recognized as safe" (GRAS) by the U.S. Food and Drug Administration (FDA) for both the crystalline and resin vitamin D_2 and vitamin D_3 in most foods. Vitamin D_3 is more commonly used in fortification. Based on current scientific evidence, FDA views the two forms as equivalent.

For vitamin D fortification FDA allows the following in food and beverages:

- *Crystalline vitamin D_2, also known as ergocalciferol*. It is produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi and is purified by crystallization. Being plant based, this form is appropriate in foods, such as soy milk, for strict vegetarians.
- *Crystalline vitamin D_3, also known as cholecalciferol*. Isolated from fish-liver oils, it is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is

purified by crystallization. This form of vitamin D also is produced endogenously in humans through sunlight activation of 7-dehydrocholesterol in the skin.

- *Vitamin D_2 resin and vitamin D_3 resin.* These are concentrated forms of irradiated D_2 and D_3 and separated from the reacting materials noted above. They are sold as food sources of vitamin D without purification.

The crystalline form is more commonly used in fortification today.

Fortification levels of vitamin D in food categories … Maximum levels for vitamin D fortification for specific categories of food are regulated by the FDA. Vitamin D ingredients, noted above, can be used as the sole source of added vitamin D within the limits noted on Tables 3 to 5. Other uses would require an amendment to the regulation in Table 3.

Table 3: How Much Vitamin D for Fortification?

Food Category	Maximum Levels of Vitamin D in Food (as served)
Breakfast cereals	350 IU/100 g
Grain products and pastas	90 IU/100 g
Milk	42 IU/100 g
Milk products	89 IU/100 g

Source: *Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Part 184 Direct Food Substances Affirmed as Generally Recognized as Safe,* as amended February 14, 2008.

In May, 2009, the U.S. FDA approved vitamin D fortification with crystalline vitamin D_2 of soy-based foods and drinks: in soy beverages, soy beverage products, soy-based butter substitute spreads, soy-based cheese substitutes, and soy-based cheese substitute products. Vitamin D_2 from plant sources is appropriate in soy products for vegans. (*See Table 4.)*

Table 4: Vitamin D Fortification in Soy Products

Food Category	Maximum Levels in Food (as served), added as vitamin D_2
Soy beverages	50(IU)/100 grams
Soy beverage products	89 IU/100 grams
Soy-based butter substitute spreads	330 IU/100 grams
Soy-based cheese substitutes and soy-based cheese substitute products	270 IU/100 grams

Source: *Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Part 172.379 Vitamin D_2,* March 16, 2009.

In addition, some other food and beverages products are approved for vitamin D_3 fortification, including infant formula, margarine, calcium-fortified fruit juices and fruit juice drinks; meal replacement bars and other bars, and soy protein-based meal replacement beverages, all positioned for maintaining body weight; and cheese and cheese products with some exclusions. (*See Table 5.)*

Table 5: Vitamin D Fortification in Other Food Products

Food Category	Maximum Levels in Food (as served), added as vitamin D_3
100% fruit juice and fruit juice drinks (not including infant juices)	100(IU)/240 moll (must also contain an established calcium level)
Soy-protein based meal replacement beverages (powder or liquid)	140(IU)/240 mL
Meal replacement bars or other-type bars for reducing or maintaining body weight	40 IU/100 g
Cheese and cheese products, excluding cottage cheese, ricotta cheese, and hard grating cheeses	81 IU/30 g

Source: *Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Part 172.380 Vitamin D_3,* Nov. 16, 2005.

Vitamin D on food labels ….Vitamin D information is mandatory or voluntary on food labels and presented in the following ways:

- *Nutrition Facts.* Unless fortified with vitamin D or carrying a nutrient content claim on the label, Nutrition Facts on food labels are not required to provide vitamin D content. As a result, consumers are likely more aware of vitamin D in fortified foods than in foods with naturally-occurring vitamin D.

  When fortified with vitamin D, however, this vitamin must be included in the Nutrition Facts panel by FDA regulation. The amount of vitamin D is listed as % Daily Value (%DV) for a standardized reference amount (label serving size), established by FDA's *Food Labeling Guidance & Regulatory Information.* (The Daily Value, which reflects the Reference Daily Intake, for vitamin D is 400 IUs for those ages 4 years and older. The Daily Value used in labeling in Canada is 5 micrograms, comparable to 200 IUs, for those ages 2 years and older.)

  With growing interest in vitamin D and the recent update of the USDA Nutrient Database to include more vitamin D values, foods with naturally-occurring vitamin D, such as more fish species and mushrooms, may voluntarily include this information on the Nutrition Facts panel.

- *Ingredient list.* Vitamin D additives must be listed on the label's ingredient list, as well as the Nutrition Facts panel, according to FDA regulations.

- *Nutrient content claim.* The food package may carry a nutrient content claim for vitamin D on the food package if it meets criteria, noted in FDA's *Guidance for Industry: A Food Labeling Guide*. According to current levels for Daily Values, a food may be listed as:
  - A "good source of vitamin D" if the food contains 10-19% of the Daily Value (40 to 76 IUs per label serving); if it meets this criterion, the terms "contains" and "provides" can also be used. A nutrient included in a nutrient content claim must also be listed in the Nutrition Facts panel.
  - "High in" vitamin D if it contains at least 20% of the Daily Value (80 IUs or more per label serving); if it meets this criterion, the terms "excellent source of" or "rich in" may also be used. Bakery products cannot labeled as an "excellent source" since the amount of vitamin D (80 IU vitamin D per reference amount for labeling) for this claim would exceed the maximum level allowed for vitamin D fortification of grain products.

- *Health claim.* Under a 2008 ruling, noted in *Guidance for Industry: Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis,* the U.S. Food and Drug Administration (FDA), has approved a health claim that communicates the benefits of calcium and vitamin D to bone health -- *if the claim*:

- Clearly states that adequate calcium and vitamin D intake throughout life, as part of a healthful diet, is essential to reducing osteoporosis risk.
- Does not imply that inadequate calcium and vitamin D intake is the *only* recognized osteoporosis risk factor.
- Does not attribute any reduction in osteoporosis risk to maintaining an adequate dietary calcium and vitamin D intake throughout life.

To make this claim, the food must be rich in both calcium and vitamin D, providing at least 200 milligrams of calcium and 80 IUs of vitamin D (for standardized reference amounts). Among other requirements, calcium must be in a digestible form. Because no foods naturally contain these nutrients at these levels, only fortified foods would qualify for this claim.

Optionally, this health claim may carry other information: the link between physical activity and reduced risk for osteoporosis; the role of adequate calcium and vitamin D intake throughout life and its link to the reduced risk of osteoporosis by optimizing peak bone mass during adolescence and early adulthood; the link to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss for persons with a family history of the disease, post-menopausal women, and elderly men and women; and the number of people in the United States, including people in certain subpopulations, who have osteoporosis or low bone density when the current information source (National Center for Health Statistics, National Institutes of Health, or National Osteoporosis Foundation) is noted.

According to FDA, the claim on foods that are excellent sources of both calcium and vitamin D might read: "Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis," *or* "Adequate calcium and vitamin D throughout life, along with physical activity, may reduce the risk of osteoporosis in later life."

- *Product name*. When vitamin D-fortified, the name of baked goods must reflect the appropriate nutrient content claim and the appropriate standardized term for the product, such as "Vitamin D Fortified Enriched Bread,"

Vitamin D Fortification: Current Regulations in Canada

Forms of vitamin D for fortification … Two forms of vitamin D are used to fortify foods.

- *Crystalline vitamin D_2, also known as ergocalciferol*. It is produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi and is purified by crystallization. Being plant based, this form is appropriate in foods, such as soy milk, for strict vegetarians.
- *Crystalline vitamin D_3, also known as cholecalciferol*. Isolated from fish-liver oils, it is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization. This form of vitamin D also is produced endogenously in humans through sunlight activation of 7-dehydrocholesterol in the skin.
- *Vitamin D_2 resin and vitamin D_3 resin.* These are concentrated forms of irradiated D_2 and D_3 and separated from the reacting materials noted above. They are sold as food sources of vitamin D without purification.

The crystalline form is more commonly used for fortification.

Vitamin D fortification levels: Foods allowed and fortification levels ... Vitamin D fortification is mandatory in some foods, and voluntary in others. *Food and Drug Regulations*, (FDR) D.03.002 identifies those foods to which vitamin D may be (voluntary) or must be (mandatory) added -- and it specifies levels as noted in Table 6. Note: calcium may be voluntarily added to some flours.

Table 6: Vitamin D Fortification: Mandatory and Voluntary Levels

Food *	Levels of Vitamin D in Food **
Margarine and similar butter substitutes	*Mandatory*: 530 IU/100 g
Milk (whole, skim, partly skimmed, evaporated)	*Mandatory:* 300 - 400 IU/reasonable daily intake of milk (Reasonable Daily Intake is defined by regulation as 30 fl. oz., or 852 ml.)
Condensed milk	*Mandatory:* May add vitamin D
Milk powder (including skim milk powder)	*Mandatory:* An amount so that a reasonable daily intake of milk contains 300 - 400 IU
Processed egg products	*Mandatory* if processing reduces vitamin D content:, To restore the amount present before processing.
Goat's milk, goat's milk powder	*Voluntary:* 35 - 45 IU/100 mL when ready-to-serve (Specific levels of vitamin A fortification are also required for skimmed goat's milk and milk powder; and vitamin D for evaporated products)
Beverages derived from legumes, nuts, cereal grains or potatoes to which a vitamin or mineral nutrient has been added	*Mandatory:* Vitamin D, as well as vitamin A, vitamin B_{12}, riboflavin, calcium, zinc (This is an Interim Marketing Authorization.)

Source: Department of Justice. Regulations Respecting Food and Drugs (C.R.C., c. 870), Ottawa, Canada, current as of November 18, 2009

* Mandatory levels of vitamin D are also provided for infant formula, formulated liquid diets, food for very low energy diets, and meal replacements.

** For some mandatory requirements, the levels identified in the regulations may be achieved without adding nutrients.

Vitamin D on food labels and in advertising … As of December, 2007, nutrition labeling became mandatory in Canada for all prepackaged foods. Mandatory or voluntary vitamin D information on food labels must be presented in the following ways:

- *Nutrition Facts table.* By Canadian Food Inspection Agency regulation, vitamin D must be included in the Nutrition Facts when the food label (including the ingredient list or any advertisement) carries any mention, statement, claim, etc., about vitamin D. Vitamin D also must be declared when shown as a component of one of the ingredients (except flour) of a prepackaged product. As a result, consumers are likely more aware of vitamin D in fortified foods or foods with vitamin D-related claims, than in foods with naturally-occurring vitamin D.

  The amount of vitamin D is a combined total of both the naturally occurring and added vitamin D in a food. Formerly expressed in International Units (IU), vitamin D is measured in micrograms (µg). with 1 microgram (µg) of either ergocalciferol (vitamin D_2) or cholecalciferol (vitamin D_3) being equal to 40 IU vitamin D.

- Stated as "Vitamin D" or "Vitamin D," the amount is percentage of the Daily Value (DV) per stated serving size. The amount may be rounded: 1)) when less than 2% DV -- if the product contains less than 1% of the Daily Value per reference amount and per serving of stated size , to "0 %", and in all other cases, to the nearest multiple of 2%; 2) when 2% to 10% DV, to the nearest multiple of 2%; 3) when 10% to 50% DV to the nearest multiple of 5%, and 4) when more than 50% DV to the nearest multiple of 10%.
- The amount of vitamin D in the Nutrition Facts is listed as % Daily Value (%DV) for the stated label serving size, noted in the *Guide*. (The Daily Value in Canada for vitamin D is 5 micrograms (µg) per day for those ages 2 years and older; for those less than two years, it is 10 µg per day.) The Daily Value, which is synonymous with Recommended Daily Intake (RDI) in Canada for vitamins and mineral nutrients, is a reference amount used in labeling. Table 7 contains IU of vitamin D converted to µg, along with a calculation of the % Daily Value (Canadian) of vitamin D for adults and children.

Note: The Daily Values for Canada differ from those in the United States. In Canada, the % DV are based on the 1983 Recommended Daily Intakes for Canadians, while in the U.S. they are based on the 1968 U.S. Reference Daily Intakes. In the U.S. the Daily Value for vitamin D is 400 IUs, which is comparable to 10 µg, for those ages 4 years and older.

Table 7: Conversion Table for Vitamin D

IU	µg	% DV ≥2 years of age*	% DV < 2 years of age**
4	.10	2	2
10	.25	6	2
20	.50	10	6
30	.75	15	8
40	1.00	20	10
50	1.25	25	15
60	1.50	30	15
70	1.75	35	20
80	2.00	40	20
90	2.25	45	25
100	2.50	50	25

* Rounding rules have been applied to these figures. The Recommended Daily Intake of vitamin D for persons of two years of age or older is 5 µg.
** Rounding rules have been applied to these figures. The Recommended Daily Intake of vitamin D for persons less than two years of age is 10 µg.

Source: *Guide to Food Labeling and Advertising*, Chapter 6, Table 6-16, Canadian Food Inspection Agency

- Serving sizes in Canada's *Guide to Food Labeling and Advertising* are usually presented as a range. This allows manufacturers some flexibility for products of varying density and size, such as cookies or slices of bread. To avoid misleading consumers, the same serving size should be used whenever a serving size is mentioned on the label, e.g. in the Nutrition Facts table, the directions for use, etc.

➢ *Ingredient list.* For prepackaged foods approved for Vitamin D fortification, vitamin D must be listed at the end of the ingredient list, in any order with spices, seasonings and herbs (except salt), natural and artificial flavors, flavor enhancers, food additives, and other vitamin and mineral nutrients and their

derivatives or salts. The ingredient list must be shown in both English and French unless exempted by the *Food and Drug Regulations* [B.01.012].

Current regulations do not allow vitamin D fortification of bakery products. As a result, vitamin D would not appear as a nutritive additive in the ingredient list.

- *Nutrient content claim.* The food package may carry a nutrient content claim for vitamin D on the food package if it meets criteria, noted in Canada's *Guide to Food Labelling and Advertising.* A nutrient included in a nutrient content claim must also be listed in the Nutrition Facts panel. According to current levels for Daily Values, a food may be noted as (see Table 8):
  - "Contains" or "source of" vitamin D if the food contains 5% DV (RDI) or more for vitamin D per stated label serving.
  - A "good source of" or "high in" vitamin D if the food contains 15% or more of the Daily Value (RDI) for vitamin D per stated label serving.
  - "Excellent source of," "very high in," or "rich in" vitamin D if it contains 25% or more of the Daily Value (RDI) for vitamin D per stated label serving.

  Current regulations do not allow vitamin D fortification of bakery products. Unless enough vitamin D comes from vitamin D-fortified ingredients, such as milk or margarine, vitamin D levels are likely inadequate in most bakery foods to carry a nutrient content claim for vitamin D.

Table 8: Vitamin D Nutrient Content Claim: Minimum Levels*

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	Recommended Daily Intake (RDI), synonymous with Daily Value (DV)	"a source of" "contains" ($\geq$ 5% RDI)	"a good source of" or "high in"or ($\geq$ 15% RDI)	"excellent source" or "very high in" ($\geq$ 25% RDI
vitamin D	5 µg	0.25 µg	0.75 µg	1.25 µg

* For foods for adults and children two years of age or older

Source: Guide to Food Labelling and Advertising, Chapter 7, Excerpted from Table 7-15, Canadian Food Inspection Agency

- ***Nutrient function claim.*** This type of claim, formerly called biological role claims, describes the well-established roles of energy or known nutrients, essential for maintaining good health or normal growth and development. Two nutrition function claims are acceptable for vitamin D:
  - factor in the formation and maintenance of bones and teeth
  - enhances calcium and phosphorus absorption and utilization

  To carry this claim, the product must have at least 5% of the RDI (or DV), or 0.25 µg, for vitamin D. The claim must be in English and French, unless exempted from bilingual labeling.

- ***Health claim.*** Since 2003, Health Canada has allowed a health claim (as a disease risk reduction claim**)** on food labels or in advertisements, noting that a healthy diet with adequate calcium and vitamin D, along with regular physical activity, is linked to a reduced risk of osteoporosis. The *Guide to Food Labelling and Advertising* (referred to here as *Guide*).

  Current regulations do not allow vitamin D fortification of bakery foods. As a result most won't contain adequate levels of vitamin D to qualify for a health claim linking vitamin D, calcium, and bone health -- unless adequate amounts of these nutrients come from vitamin D-fortified ingredients such as margarine and milk.

Chapter 8 Health Claims*,* of the Canadian Food Inspection Agency provides the following regulations (noted in May, 2009, Summary Table of Disease Risk Reduction Claims: Table 8-1):

- *Wording*. The health claim must be worded exactly as follows. It cannot be modified, and no intervening information, graphic sign or symbol may come between parts of the claim. However, words, numbers, signs or symbols may come before or after the health claim, provided that they do not change the nature of the claim. And in the case of advertisements, all parts of the claim must be displayed in equal prominence with no parts highlighted."
  (1) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is a good source of calcium."
  (2) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is high in calcium."
  (3) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is an excellent source of calcium."
  (4) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is very high in calcium."
  (5) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is an excellent source of calcium and vitamin D."
  (6) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is very high in calcium and vitamin D."

- *Conditions for the health claim.* If a product carries a health claim or statement for vitamin D on the label or in the advertisement, by or on the direction of the manufacturer of the product; 1) *Prepackaged products*: The Nutrition Facts table on the label will include the amount of vitamin D and phosphorus, in accordance with item 14 of Table 6-2 [B.01.402(2)] of the *Guide,* and 2) *Products that are not prepackaged.* The label or advertisement will include the amount of vitamin D, calcium, and phosphorus per serving of the stated size, in accordance with section B.01.602, if applicable, of the *Guide*.

  The product may carry one of the six health claims noted above, if it meets certain nutritional criteria. Only claims (5) and (6) require a specified vitamin D level. *Per reference amount and per serving of its stated size*: the product must contain 200 mg or more calcium for claims (1) and (2); the product must contain 275 mg or more calcium for claims (3) and (4); and the product must contain 275 mg or more calcium and 1.25 µg or more of vitamin D for claims (5) and (6). Calcium amounts are somewhat higher if the product is a prepackaged meal. It also cannot contain more phosphorus (except from phytate) than calcium and must contain 0.5% or less alcohol. For reference amounts and serving sizes, refer to 6.1 of the *Guide*:

- *Language.* Disease risk reduction claims on a label must be given in both English and French unless the food is a "local food", a "test market food", or a "specialty food," as defined in the *Food and Drug Regulations*. In that case, the mandatory information only needs to be shown in one of those languages.

Vitamin D Fortification: An Opportunity for the Bakery Industry?

Fortification offers an appropriate strategy for addressing the public health concerns about the vitamin D shortfall … when added to the right foods, in the right amounts, for the right target population. The US Food and Drug Administration *Fortification Policy* and Institute of Medicine's *Guiding Principles for Nutrition Labeling and Fortification*, 2003, provides guidance for appropriate fortification. Unlike folic acid fortification in grain products, vitamin D fortification is discretionary.

Vitamin D fortification is a likely opportunity for many categories within the food industry, including the bakery industry. "Bread could be a suitable vehicle for fortification because it is a common part of diets worldwide," noted Natri et al. in the *Journal of Nutrition*, 2006. (Their research showed the bioavailability and stability of vitamin D_3, evenly distributed in fortified wheat and rye breads, despite differences in the fiber content of the breads; fortification levels in the study were higher than US fortification regulations allow.)

In its 2003 report on fortification IOM noted, "Recent studies demonstrated that the levels of vitamin D already added to food are not high enough or are not found in enough different food products to prevent vitamin D inadequacy." Since then, more vitamin D-fortified products have entered the marketplace, especially in the United States.

While fortification may be scientifically justified, however, many experts believe that more scientific investigation and answers on vitamin D status and optimal intake levels are needed before the food industry rushes to fortify. That includes consensus on appropriate fortification in all categories of food, including bakery products. To fortify and market appropriately, many issues require consideration, among them:

- *The links among vitamin D, calcium, and bone health are well documented, but scientific evidence on other health benefits for vitamin D is not yet conclusive.*

  That said, the U.S. FDA has *only* approved a health claim for calcium and vitamin D related to bone health. As currently established, bakery products are not fortified for vitamin D and calcium at levels high enough for this health claim. Other possible benefits of vitamin D need to be communicated and/or marketed within the context of emerging science – and not as a health claim at this time.

  In Canada the *only* approved vitamin D-related health claim links a healthy diet with adequate calcium and vitamin D, and regular physical activity with strong bones and reduced risk of osteoporosis. Two nutrient function claims are allowed for vitamin D. *Optimal intakes for vitamin D have not been established, although evidence shows that vitamin D status is inadequate for many. No RDAs currently exist – only AIs.* Vitamin D fortification for bakery products, and all food categories, should be scientifically justified, based on documented public health needs and the documented prevalence of nutritional inadequacy in the population.

  Updated DRIs for calcium and vitamin D from the IOM, due for release in late June, 2010, may offer increased recommendations, pending adequate scientific evidence. (Some experts suggest that vitamin D focus should include more emphasis on appropriate and safe exposure to sunlight.)

- *Vitamin D fortification across many food categories could potentially result in excessive intake levels.* Discretionary vitamin D fortification for all food categories, including bakery products, needs to be considered in relation to current dietary intake of vitamin D, the ULs (which may be updated/increased in 2010), and potential adverse effects of excessive vitamin D intake.

- *Vitamin D recommendations within the Dietary Guidelines for Americans, 20I0, is not certain*. The report from the Dietary Guidance Advisory Committee is scheduled for submission to USHHS and USDA in spring, 2010, before new DRIs are released. This potentially limits the marketing opportunity for science-based messaging related to vitamin D.

- *For the U.S. until new labeling regulations are established, the Daily Values for vitamin D will remain at 400 IU – and will not reflect possible changes in the DRIs.* Regardless, Daily Values are reference values and not nutrient intake recommendations. An opportunity: the DV of 400 IU for vitamin D is twice the AI level set by the FNB in 1997 for those ages 1 to 50 years; that level matches the current AI for adults ages 51 to 70, and the 2008 recommendations from the AAP for healthy children and adolescents.

  Daily Values in Canada are lower, comparable to 200 IU for ages 2 years and above, than in the U.S.

- *Revised DRI levels could potentially -- and eventually -- impact regulatory levels for vitamin D fortification and label claims in both the U.S. and Canada.*

  Currently in the U.S., maximum levels for grain products, including bakery products, are set by U.S. FDA at 90 IU of vitamin D per 100 grams (or about 3.5 ounces) as served. Reference amounts used for labeling vary for different bakery products. These levels of vitamin D fortification, shown in Table 9, are allowed for these bakery products:

Table 9: Vitamin D Fortification Levels in the United States for Bakery Products

Bakery product	Reference amount * (for food label/Nutrition Facts serving size)	Allowable vitamin D fortification per reference amount
Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies	55 grams	≤ 49.5 IU
Bread (except for sweet quick bread), rolls	50 grams	≤ 45 IU
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick breads, muffins, toaster pastries	55 grams	≤ 49.5 IU
Cookies	30 grams	≤ 27 IU
Crackers that are usually not used as a snack, melba toast, hard bread sticks, ice cream cones	15 grams	≤ 13.5 IU
Crackers, bread sticks (that are usually eaten as a snack)	30 grams	≤ 27 IU
Grain based bars, e.g. breakfast bars, granola bars, rice cereal bars	40 grams	≤ 36 IU
Pizza crust	55 grams	≤ 49.5 IU
Waffles	85 grams	≤ 76.5 IU

* The use of reference amounts in food labeling standardize information for product comparisons.

For reference amounts for other bakery products, see National Archives and Record Administration. Electronic Code of Federal Regulations e-CFR, Title 21: Part 101 Food Labeling, updated October 28,2009.

If one label serving has at least 10% DV, or 40 IU, a bakery product can be labeled as a "good source" of vitamin D. As noted earlier, bakery products cannot labeled as an "excellent source" since the amount of vitamin D needed (80 IU vitamin D per label serving) for this claim would exceed the maximum level for vitamin D fortification of grain products allowed.

The U.S. FDA also provides regulations for vitamin D fortification of enriched cornmeal and enriched farina, noted in the Electronic Code of Federal Regulations e-CFR, *Title 21: Food and Drugs. Part 137 Cereal Flours and Related Products.*

- In Canada grain products, including bakery products, are not identified in the *Regulations Respecting Food and Drugs* as a food category that can be voluntarily fortified with vitamin D. However, the IOM acknowledges that food fortification in Canada has been tightly regulated, but also notes that the situation is changing. The result may be more options for discretionary fortification in the future

- In addition*, the bakery industry needs to determine whether baked foods are appropriate for discretionary vitamin D fortification -- and if so, which products*. Milk is an appropriate food for vitamin D fortification because it naturally contains significant amounts of bone-building nutrients (calcium, phosphorus, magnesium); bakery goods do not*.* Except for fortified breakfast cereals in the U.S., grain products are not readily recognized as sources of vitamin D.

- *If vitamin D fortification moves forward in the bakery industry, manufacturers must also consider …*
  - *Form of vitamin D.* Current labeling laws treat vitamins D_2 and D_3 equivalently and interchangeably; both forms are approved in the U.S. for bakery products. While vitamin D_3 often noted as more bio-available, scientific evidence on bioavailability of one form over another is not conclusive. Either form as a crystalline may be more cost effective than vitamin D in a resin.
  - *Standardizing vitamin D fortification levels in various bakery foods, as the dairy industry has done for milk.* The U.S. FDA allows a range of vitamin D fortification: equal to or less than 90 IUs of vitamin D per 100 grams of bakery product. Standardized levels for specific products may help consumers make comparisons and decisions about vitamin D-fortified foods. If fortification is allowable in bakery products in Canada, the same would be true.
  - *A fortification process that allows for controlled levels of vitamin D. Adding vitamin D to flour allows cont*rol, as product formulations vary among bakery products.
  - *Determination of the right bakery products for the targeted population.* For example, are vitamin D-fortified bread and bakery products appropriate and approved as school breakfast and lunch items, or are bakery products approved for the Women, Infants and Children (WIC) Program in the U.S.? How does the gluten-free movement impact the consumption and types of bakery products? What bakery *p*roducts are more often consumed by older adults and by cultural groups at risk for lower vitamin D status? *Fortifying with appropriate levels of calcium, as well as vitamin D.* Vitamin D and calcium work as partners in bone health.

- *Consumers need science-based guidance on vitamin D* -- including how to use food labeling to identify, compare, and choose vitamin D-fortified foods and how to incorporate these foods into an eating plan. While U.S. consumers are increasingly aware of vitamin D and bone health (as noted by the *IFIC Functional Foods/Foods for Health Consumer Trending Survey,* 2009), vitamin D in today's media can lead to confusion about appropriate intake levels and health benefits. Often single studies about vitamin D provide health headlines, even though evidence-based advice is not yet available*.* If the bakery industry contributes significantly to discretionary vitamin D fortification, an effective, science-based consumer information effort for vitamin D fortification related to bakery foods will be needed by the bakery industry in partnership with other nutrition education efforts.

.*** * ***

Bottom line: Vitamin D fortification can play a substantial role in addressing public health concerns about vitamin D status. Regulations are in place for discretionary vitamin D fortification of bakery foods in the U.S., but not in Canada. Yet with many unknowns, the bakery industry is wise to proceed with caution until more science-based guidance is released. Standardized vitamin D levels can contribute to decisions about fortified products. Evidence-based consumer marketing and communication messages about vitamin D will be an essential part of fortification initiatives.

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Resources

American Academy of Pediatrics. Guidelines for vitamin D intake. _Pediatrics. 2008;122:1142-1152.Calvo MS, Whiting SJ, Barton CN. Vitamin D fortification in the United States and Canada: current status and data needs. American Journal of Clinical Nutrition, 2004;80:1710S-6S.

Canadian Cancer Society. Canadian Cancer Society announces vitamin D recommendation. http://www.cancer.ca/canada-wide/about us/media centre/cw-media releases/cw-2007/canadian cancer society announces vitamin d recommendation. June 8, 2007.

Canadian Food Inspection Agency. Guide to Food Labelling and Advertising, Ottawa, Canada.

DeLuca HF, Zierold C. Mechanisms and functions of vitamin D. Nutrition Review, 1998:56:S4-10.

Department of Justice. Regulations Respecting Food and Drugs (C.R.C., c. 870), Ottawa, Canada, current as of November 18, 2009.

Dietary Guidelines Advisory Committee. Meeting 2 comment summaries, January 29-30, 2009.

Dietary Guidelines Advisory Committee. Meeting 4 presentations, November 4, 2009.

Geller, J, Pressman, P. Vitamin D: the sunshine hormone. Food Technology, 2007;61(6):21.

Health Canada. Vitamin D and health. September 24, 2007, http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2007/2007_130-eng.php

Health Canada (Santé Canada). Vitamin D: Recommendations and review status. July 23, 2009. http://www.hc-sc.gc.ca/fn-an/nutrition/vitamin/vita-d-eng.php

Heaney RP. Vitamin D in health and disease. Clinical Journal of the American Society of Nephrology, 2008; 3: 1535-1541Holick, MF. Vitamin D deficiency. New England Journal of Medicine, 2007;357 (3):266-281.

Holick, MF, et. al. Vitamin D2 is as effective as vitamin D3 in maintaining circulating concentrations of 25-hydroxyvitamin D. The Journal of Clinical Endocrinology & Metabolism. 2008;93(3):677-81.

Houghton LA, Vieth R. The case against ergocalciferol (vitamin D2) as a vitamin supplement. American Journal of Clinical Nutrition, 2006;84:694-7

Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes: Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride. Washington, DC: National Academy Press, 1997.

Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification. Washington, DC: National Academy Press, 2003.

International Food Information Council Foundation. *IFIC Functional Foods/Foods for Health Consumer Trending Survey,* Washington, DC: 2009.

L'Abbé, MR, et al. The Canadian health claim for calcium, vitamin D and osteoporosis. Journal of the American College of Nutrition, 2004; 23:303-308.

National Archives and Record Administration. Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Part 184 Direct Food Substances Affirmed as Generally Recognized as Safe, updated October 27, 2009.

National Archives and Record Administration. Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Subpart D—Special Dietary and Nutritional Additives, current as of November 4, 2009.

National Archives and Record Administration. Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Part 101 Food Labeling, current as of November 4, 2009.

National Archives and Record Administration. Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Subpart B 104.2 Fortification Policy, current as of November 4, 2009.

National Archives and Record Administration. Electronic Code of Federal Regulations e-CFR, Title 21: Food and Drugs. Part 137 Cereal Flours and Related Products, current as of November 4, 2009.

National Osteoporosis Foundation. http://www.nof.org/osteoporosis/diseasefacts.htm. 2009.

National Osteoporosis Foundation. National Osteoporosis Foundation's updated recommendations for calcium and vitamin D intake. http://www.nof.org/prevention/calcium_and_VitaminD.htm. October, 2008.

Natri, A, et al., Bread fortified with cholecalciferol increases the serum 25-hydroxyvitamin D concentration in women as effectively as a cholecalciferol Supplement. Journal of Nutrition, January,2006;136:123-127

Office of Dietary Supplements, National Institutes of Health. Dietary Supplement Fact Sheet: Vitamin D. Washington, DC, http://ods.od.nih.gov/factsheets/vitamind.asp, updated 9-11-09

Statistics Canada. Canadian Health Measures Survey: Vitamin D blood plasma concentrations in the population. The Daily. July 2, 2009, http://www.statcan.gc.ca/daily-quotidien/090702/dq090702a-eng.htm.

U.S. Department of Agriculture, Agricultural Research Service. USDA Nutrient Database for Standard Reference, Release 22. Washington, DC, October, 2009.

U.S. Food and Drug Administration. Guidance for Industry: A Food Labeling Guide April 2008

U.S. Food and Drug Administration. Guidance for Industry: Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis, May 2009.

Yetley, EA. Assessing the vitamin D status of the US population. American Journal of Clinical Nutrition, 2008;88 (supplement):558S-64S,.

Yetley, EA, et. al. Dietary Reference Intakes for vitamin D: justification for a review of the 1997 values. American Journal of Clinical Nutrition, 2009; 89:719-727.