Functional Foods and Nutraceuticals
NUTR/FOOD*4090

MIDTERM EXAMINATION
Feb. 11, 2016, 10:00 – 11:20 PM

ANSWER KEY

(8) 1. What are the key components of the definitions of "Functional Foods" and "Nutraceuticals", as defined by Health Canada? How do these relate to "foods", "Novel Foods" and "Natural Health Products"? Use examples to support your answer.

Key concepts are underlined. *You didn't need all the words, but you did need the right concepts*.

(2) A functional food is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions (the last part is critical – *beyond basic nutritional function*). The basic nutritional function of a nutrient is its main physiological role in the body, and typically it is associated with an acute deficiency if we don't have enough. "Beyond that" refers to the physiological role of a bioactive component or nutrient that would sustain health or reduce the risk of chronic diseases. (*too much detail here, just make sure they have the concept – examplses help to ensure they have it right*

(2) A nutraceutical is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease. *It could also be called the "bioactive" component*.

(2) A novel food is a food that does not have a history of safe use as a food, or includes an ingredient that does not have a history of safe use. Functional foods might therefore be also considered as novel foods and need to demonstrate safety before approval for consumption.

(2) A Natural Health Product is a naturally occurring substance that provides a pharmacological activity or other direct effect in diagnosing, treating, mitigating, or preventing a disease, disorder, or abnormal physiological state or its symptoms in humans; restoring or correcting organic functions in humans; or modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. Nutraceuticals are a subset of NHPs.

(4) 2. Besides the information contained in the definitions in Question 1 above, what other factors might need to be considered in deciding if a Functional Food or Nutraceutical is physiologically-functional?

Issues *(1 pt for each of up to 4 – they needed to be articulated well for the full point)*:

- How do you distinguish between basic nutritional function (normal growth and maintenance – *usually associated with a deficiency disease if not consumed at sufficient quantity*) and physiological benefits beyond that?
- what is the effective dose of the bioactive to have a therapeutic effect and can it be obtained from the food by regular consumption? How much would be required and how often?
- Does a consumer have to be at risk for the chronic disease for the food to be functional for that person? And, how do you know you are "at risk"?

- Can a health claim be made? How else do people know what is functional? Who do you trust to make that statement?
- Can you just look at the functionality of an individual food or do you also have to consider diet?
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- *There may be others that would also be okay, if articulated well and they make sense in this context.*

(4) 3. Health Canada has recently approved several new Therapeutic Health Claims for foods in Canada. Provide a general definition of a Therapeutic Health Claim and two examples of these new claims.

Therapeutic Claims are about treatment or mitigation of a disease or health-related condition, or restoring/correcting a body function. The person has the disease or condition and functional food helps to alleviate it (*e.g., you can only lower blood cholesterol if it is high already*). (2 pts)

Examples (1 of, for 1 pt):

- Plant Sterols (Phytosterols) and Blood Cholesterol Lowering
- Oat Products and Blood Cholesterol Lowering
- Psyllium Products and Blood Cholesterol Lowering
- Unsaturated Fat and Blood Cholesterol Lowering
- Barley Products and Blood Cholesterol Lowering

(4) 4. The US regulations around health claims include a category called "Qualified Health Claims" – what are these claims, what does the term "qualified" mean in this context, and what does the FDA focus on when allowing such claims?

Qualified Health Claims – emerging evidence but not sufficiently established for a SSA health claim. The qualifying language in the claim is included to indicate that the evidence supporting the claim is limited, e.g., "…might reduce…. but there is very little scientific evidence for this claim". Statements "must be truthful and not misleading". The claim must include the qualifying language, and usually "This statement has not been evaluated by the FDA, and this product is not intended to diagnose, treat or cure any disease". *(3 pts for this concenpt, well articulated)*
The focus when allowing these claims is safety, not efficacy. *(1 pt)*

(5) 5. What is meant by "bioaccessibility" and by "bioavailability"? What factors influence these parameters and how could they be improved?

Bioaccessibility - the fraction of a digested nutrient that is available for absorption in the small intestine after digestion. The bioactive has to be liberated from the food matrix and solubilized in the small intestinal lumen. *(1 1/2)*
Bioavailability - the fraction of a digested nutrient that is available for utilization in normal physiological functions or storage in the body, hence bioaccessibility is also accounted for, eg., bioavailability is usually less than bioaccessibility, but cannot be greater than. The bioactive has to be absorbed across the mucosa intact to reach the active site, or has to be transformed after absorption to the active form. *(1 1/2 pts for this concept)*

These can be influenced by the chemical and physical forms of the bioactives in the food matrix, interactions with other ingredients, effects of processing and cooking methods (pH, heat), and conditions in the GI tract. Thus accessibility/availability can be improved by addressing these factors within the product matrix. *(2 pts for this concept)*

(5) 6. Your company is considering the manufacture and sale of an isolated nutraceutical extracted from a natural source. There are several extraction and concentration methods available. How would you decide what was most appropriate? Provide some examples.

Considerations in the selection of methods would be whether it is volatile or not, the difficulty in solubilizing the material in water or solvent, the purity required, the sensitivity of the bioactivity or bioavailability to changes in environment (pH, temperature, ionic strength, etc.), waste streams generated and the cost. *Other concepts acceptable too, if they make sense in this context (3 pts)*

A few of these should be mentioned with enough description to demonstrate some understanding of methodology (2 pts)
Extraction methods:

- Distillation and Steam distillation; for extraction of volatiles from liquid or solid substrates, based on differential boiling points of the volatiles. Steam uses Dalton's law of partial pressures to lower the boiling points of the volatiles, for sue with heat sensitive volatiles.
- Low pressure solvent extraction (solid-liquid or liquid-liquid); Uses a solvent (acetone, ethanol, 1-propanol, 2-propanol, ethyl acetate, propyl acetate) to extract non-water soluble components. Can be stirred-tank or percolation systems. Solvent is evaporated off and recovered.
- Supercritical fluid extraction; Very complex system that employs temperature and pressure to extract materials with supercritical solvents (e.g. CO2). SC Fluids have solvation properties of a liquid but diffusion properties of a gas. System is expensive but very effective and safe.
- Adsorption/desorption methods (e.g., ion exchange). Employs a resin for to adsorb materials, then a rinsing stream to desorb them, e.g., based on charge (ion exchange). Can be stirred tank or column.

Concentration methods:

- Vacuum evaporation
- Ultrafiltration/Membrane processing
- Spray or freeze-drying.

(10) 7. Your company, which is a market leader in bottled functional beverages, is excited about a berry from South America that is known indigenously to enhance vitality ("it's good for you!"). The berry has a sharp, sour taste. As product development manager, you are tasked to investigate the potential for its use in your products. What questions do you need to address in deciding if you will be able to develop a successful product with this berry?

There were several types of approaches to responding to this question. The important thing is that the answer was well thought out, addresses a path similar to that below, and was well articulated. Marks reflected completeness of response, not specific numbers of bullets.

These are the points I would address:

- What is meant by "vitality", and how can that message be delivered to potential consumers? Can you develop a market for it?
- Is there any science to back up the claim? Important – but – it would not be the job of product development to assess that, only to trust the literature, so, don't suggest developing any intervention trials.
- Supply of the berry – is it wild or domesticated? Is it available in good supply or can more be grown? What effect on the local environment, etc.?
- Is the sharp, sour taste objectionable or can it be masked or reduced? Are there any textural considerations that would affect its sensory quality once incorporation into the beverage? "Taste is king"
- Can the berry be used whole as a juice with simple filtration or how much processing is needed to get it into a beverage? Any potential to extract the bioactive, and if so, how?
- How is it going to interact with other beverage ingredients?
- Bioavailability/efficacy of the bioactive ingredient once it's in a beverage? Is there any data on effective dose?
- Effects of beverage processing on bioavailability – is it heat stable? pH stable?
- Product stability/shelf life considerations.
- Consumption patterns of the intended audience – how do you specifically target people at risk for CVD?
- Any effects of under-consumption or over-consumption? Side effects?
- Cost to consumer and profit potential once developed.

(8) 8. In the guest lecture by Dr. Jenny Gusba from PepsiCo, she discussed several important considerations and challenges for multi-national companies of bringing one of their own functional foods developed for one market, for example the United States, into Canada. Using specific examples to support your answer, identify and explain some of these challenges.

1 mark challenge, 1 mark example (x4)
0.5 if the challenge or example is vague,

- Cost is key
    - Need to ensure a 'full production run' to make the profit margins sufficient, but the consumer demand may not be sufficiently high in Can vs US to necessitate the full batch.
- Regulations are different in Canada vs USA
    - Eg: some novel fibres count as a fibre source in US but not in Canada
- Safety approval for food additives not the same in all countries
    - Eg: stevia wasn't approved in Canada as early as it was in US
- Serving sizes are different
    - Eg: cant say calorie free if 5kcal in our serving
- Canada labeling has to be French and English
    - Often crowds the message on the front of packaging
- Health claim wording is different in Canada and US
    - Eg: cheerios packaging is different
- Challenges with consumer education
    - Might be a great idea, but if consumers don't understand the science, the message might be lost (eg: n-3 health benefits took a long time to recognize)

(12) 9. You have observed that people you know who eat a lot of fruits and vegetables seem to have a lower rate of cancer compared to the people you know who eat a lot of red meat. As a budding scientist, you are keen to test out this hypothesis, but realize that starting with a human clinical trial is very expensive and not feasible as a first step. Instead, you decide to start with a combination of cell culture and animal studies to build your case. Based on concepts and models discussed in class, briefly outline the design of 1 cell culture study AND 1 animal study to test your observation. For each study – be sure to identify the specific research question being tested, and provide your rationale/an explanation for why you made the choices you did. (Answer on next page)

Cell culture study (6 marks)

RQ: (1 mark)

Design: 5 marks (1 point per element w justification)

Animal Study (6 marks)

RQ: (1 mark)

Design: 5 marks (1 point per element w justification)