The Food-NHP Interface

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Introduction

I wanted to set down on paper some recent developments at Health Canada with regard to how food and natural health products (nhp's) are currently being regulated, and how this is going to change in the years ahead. At the time of writing, there is a sea change in how the Food Directorate (FD) and Canadian Food Inspection Agency (CFIA) are viewing health claims on food and what constitutes a "food ingredient" in light of previous years.

We are currently in the ninth year of nhp regulation under the Natural Health Products Directorate (NHPD). Especially in the last five years, food products that contained added nhp ingredients (such as amino acids or vitamins) were accordingly non-compliant foods, but the NHPD accepted NPN submissions for these. Such products were difficult to classify as either nhp's or foods, as they seemed to be on the cusp of either – and were called **food-like natural health products** while treated as nhp's. However, in the last several years the NHPD had halted reviewing such submissions, with the intent of transitioning these products completely over to the food category.

This year, the NHPD and FD have been working together to transition these products. The first products to be transitioned were the **caffeinated energy drinks** (CED's) like Red Bull, and which was very specific in the requirements for transitioning over (e.g., caffeine limits, required warnings). However, there are quite a few other products that were formerly treated as nhp's, but which are now in process of being transitioned over to foods – including powders, liquids, gum and bars. This document will attempt to provide clarification on four major questions:

1. Is a product a food or an nhp?
2. Is a product a non-compliant food?
3. How are non-compliant foods handled, and what regulatory processes are available for non-compliant foods?
4. What health claims can be made on food?

I would like you to please keep in mind that much of the content in this document is not officially published by Health Canada, and is based on in-person meetings with the Food Directorate and NHPD. The Submission Management and Information Unit (SMIU) of the Food Directorate can be reached at SMIU-UGDI@hc-sc.gc.ca and they can confirm much of what is here. I will try to separate out my impressions/opinions from what we know to be facts.

Should you have any questions please feel free to email me directly at brian@nhpconsulting.ca or phone me at 587-350-1506.

Who's Who

There are four government departments that play into the regulation of food and nhp's. The **Natural Health Products Directorate** (NHPD) regulates nhp's – they generate policies and standards of evidence for safety and efficacy, issue product licences (NPN's), and issue site licences for manufacturers and importers. The **Health Products and Food Branch Inspectorate** (HPFBI) – usually simply referred to as "the Inspectorate" – is responsible for compliance and enforcement for nhp's and drugs (but not foods).

The **Food Directorate** (FD) is responsible for issuing policies and regulations governing food products, while the **Canadian Food Inspection Agency** (CFIA) is responsible for enforcing the food regulations. Keep in mind that the CFIA often plays a guiding role in food regulation as well, helping stakeholders understand food regulation. Typically the FD has a more "background" role, while the CFIA is more engaging with industry. The FD is the body responsible for providing the CFIA with decisions relating to novel foods and health claims on food.

Note that the NHPD, HPFBI and FD are all branches within the same bureau, the **Health Products and Food Branch** (HPFB) of Health Canada.

What is a Food?

It may surprise you, but there is no precise definition of a food in the *Food and Drugs Act* or in the *Food and Drug Regulations*. There is a definition, but it is a self-referencing (i.e., cyclical) definition. Basically, "a **food** includes any article … for use as a food or drink".[1] In other words, if it has been consumed as a food historically, it's a food. This is a very broad definition, and it was always intended to be broad so as to not limit what some people eat as food. With the diversity of cultural backgrounds in Canada, there is certainly a multitude of different items that people consume as "food".

We can also gain some insight on what a food is, by what a food is not. A **novel food** is term applied to foods that either do not have a history of safe use as a food, or which result from a process not previously used for food, or else are genetically modified foods.[2] So, if a product does not have a safe history of use as a food, then it would be considered a novel food. We can therefore deduce that part of the definition of a food is that it has a history of safe use as a food.

Also, a food is permitted to have certain added ingredients that help preserve the product, impart flavour or texture, etc. These are called **food additives**, and there is a specific list of ingredients that are available to choose from in the *Food and Drug Regulations*.[3] (Note that spices and flavouring agents are not food additives, and are permitted in foods.)

This is where the *Food and Drugs Act* and *Food and Drug Regulations* end. Over the years, the Food Directorate and Canadian Food Inspection Agency have published guidance documents and tools, to help stakeholders understand their interpretations of the law. Keep in mind that Health Canada has the authority designated to them, to interpret these laws in their day-to-day regulation of the industry. One document published a few years ago, was the *Food-Natural Health Product Interface* document, which introduced the concept of a food having a **food format** and also as **food purpose** – however, these are also rather cyclical definitions. According to them, a food format is "a format and serving size consistent with food use", and a food purpose is "a purpose that has been established by history of use, or being regulated, defined or implied by the *Food and Drug Regulations*.

It is difficult to interpret these statements, and at the end of the day, it all comes down to practical experience with Health Canada. I will leave these formal definitions behind for now, and will focus on the definitions that have been offered to us from in-person meetings. There is indeed a fairly high degree of predictability in classifying a product as a food vs. an nhp, but it needs some explaining.

[1] *Food and Drugs Act*, Section 2.
[2] I.e., GM foods which produce a "major change" in their behaviour or properties. Not all GM foods are novel foods.
[3] Division 16.

Food Formats

In deciding whether a product is a food or natural health product, there are four major factors to consider. First, it has to be in a food format – i.e., powder, liquid, gum, bar or a format that is traditionally seen as food (e.g., bread, juice, eggs, cereal). Secondly, it has to be represented as a food in its packaging, advertising and where it is sold. I will deal with each of these factors in turn, but at the end of the day, if it "acts like a food and talks like a food, it's a food" (the same is true for ducks). Thirdly, how it is perceived by the public (history of use). And lastly, the composition of the product itself (i.e., if its ingredients are considered food ingredients).

Products that are in a format that are obviously food, shouldn't need clarification here. If you added glucosamine to baked bread, for example, it's still bread (and is a food). If you added a probiotic to a gum, it's still a gum (and is a food). If you add calcium to orange juice, it's still orange juice (and is a food). They may be non-compliant foods, but they're still foods (i.e., not nhp's).

Where it becomes difficult is where foods and nhp's share dosage forms at times. In particular, these are powders and liquids. With powder or liquid products, the dosage form alone cannot classify the product, and so the product's representation (see below) is what determines classification. It is helpful, though, to discuss these dosage forms in turn.

Liquids

Not all liquids are beverages of course; tinctures are a good example. But if the highest quantity ingredient in the product is water, you should know that there is a strong chance that it is a food. Liquids are more rigorously seen as foods than say powders (which are harder to classify). Unless it is a tincture, it is safe to say that a liquid product will be treated as a food.

There are exceptions, of course, and they are worth mentioning here. **Small containers** (under around 90 mL / 3 fl. oz.) are typically seen as "shots", and are not regulated as food. Energy shots and protein shots are good examples, which are treated as nhp's and not foods. **Caffeinated energy drinks** (CED's) are regulated as food (not nhp's), and have a caffeine content between 200 and 400 ppm (among other criteria), such as Red Bull. Keep in mind, though, that **energy shots** are not considered CED's, and so if the volume is less than around 90 mL it would be considered an nhp (not a food).[4] **Liquid vitamin/mineral** products that do not contain any calories, and are just minerals/vitamins in a liquid format (e.g., liquid ionic calcium), and these are treated as nhp's. **Distilled oils**, such as oil of oregano, are mostly seen as nhp's, though pressed oils (such as flax oil and borage oil) that can be used as cooking oils would be considered food.[5] And of course, **tinctures** would still be considered nhp's.

Also, **liquid sports nutrition products** (e.g., exercise recovery drink) would most likely be treated as foods in most circumstances.

Other than these specific exceptions, liquid products will definitely be viewed as foods, not nhp's. For example, a standardized herbal tea in a drinkable beverage format would be considered a food (e.g., rhodiola beverage), even if the herb is standardized.

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[4] There is no formal volume cut-off for shots, but the NHPD is using the 90 mL mark as the rule of thumb (100 mL is still possible but is pushing the boundary).

[5] **Fish oil** in a liquid format would still be considered an nhp because of its known medicinal purpose (it does not really have a historical food use).

Powders

Powders are the most difficult category to classify right now, and this is where the Food Directorate is experiencing the greatest learning curve. It is best to deal in specific examples. **Powdered drink mixes** will be treated as foods, even if they are just vitamins and minerals (e.g., Emergen-C®) – if it is a mix that you put into water that becomes a beverage, it's a food. **Powder sports nutrition products**, however, will by and large be treated as nhp's – this is an interesting exception, and my understanding is that the Food Directorate considers these too much like nhp's to treat them as food. **Greens products** that you mix with water and drink, will be treated as food. **Protein powders**, including **vegan protein powders**, that you mix with water and drink, will be treated as food, even if they contain what we would consider nhp medicinal ingredients (e.g., amino acids, vitamins).

Meal replacement powders that you mix with water and ingest as a substitute for a meal, are foods – however, keep in mind that there are very tight compositional requirements for meal replacement products, as they are considered a more sensitive category of products that vulnerable populations may lean too heavily on.[6]

Teas

Teas can go either way. A **medicinal tea**, i.e. a tea that has a very specific medicinal purpose and is represented as such, would be considered an nhp – though keep in mind that my impression from the Food Directorate is that even medicinal teas could be treated as food, if the manufactured desired this. **Other kinds of teas** (e.g., chamomile tea, valerian tea) would be considered food products.

Gum

Gums are almost always going to be treated as food. The only exception would be **nicotine gum**, which the Food Directorate considers an nhp because it is only sold in pharmacies. Chewing gum that contains an nhp medicinal ingredient (e.g., probiotic, mineral, amino acid) would still be treated as a food, unless it were sold only in pharmacies and had a narrow margin of safety (and had a very specific therapeutic purpose).

Bars

Bars will almost always be treated as food, with no exceptions that I can think of. By "bar", I mean a product in the form of a chocolate bar or protein bar, which contains macronutrients among other ingredients.

[6] *Food and Drug Regulations*, Division B.24.200.

Product Representation

If a product is "represented" as a food, it will be treated as a food. Many factors play in here, such as:

- If the label says it is a "beverage" or "drink mix" or "drink", it would be treated as a food.
- If the product delivers a significant amount of Calories (e.g., protein, carbohydrates, fats), it would likely be treated as a food.
- If the product is sold at the retail level next to other food products – such as in a grocery aisle (as opposed to a supplement aisle) – it would be treated as a food.
- If the product has a very specific dosage that would be unsafe to consume *ad libitum* (without limit) and requires warnings, the product would likely be treated as an nhp. (However, this last point is not as cut and dry as the other points, and foods which require dose instructions can still be considered foods.)

These generalizations may appear confusing, but if specific products are analyzed in terms of both its format and representation, you will actually find there are not many products that have an uncertain classification.

What is Allowed in a Food

This is where we are seeing a shift in policy. It is still true that in order for a food to be a **compliant food**, it has to have valid food ingredients (i.e., no novel ingredients) and pre-cleared food additives. However, the CFIA and FD are modifying their views on what might be called a **food ingredient**, which deserves some explanation.

The Food Directorate and CFIA seem to be altering their perspective on what ingredients can be considered acceptable food ingredients.[7] Keep in mind that by definition, a food is something that has been historically safely consumed as a food – but also keep in mind that this definition does not specify quantities of food consumed, or what countries or people have consumed the food, or a timeframe over which the food has been consumed. This leaves the definition very open. For example, in the United States, dietary supplements are a subclass of food – and so in theory, any dietary supplement sold in the US could be grounds for classifying it as a food ingredient.

This may sound ground-breaking, but let me assure you this is how Health Canada is leaning. For example, L-creatine is an amino acid that has been on the market in the US as a dietary supplement for many years and has many double blind studies behind it (supporting "safe use") – and it is also a natural part of the human diet. L-creatine, then, by this definition would be regarded as an acceptable food ingredient.

Another example is soy protein – soy protein has been on the market in the US for a long time, and isolated soy protein has been safely consumed as a food for a healthy period of time. It is present in soy, of course, and by these definitions would not be considered a novel ingredient (i.e., it would be an acceptable food ingredient).

Of course, ingredients that have a specific purpose of conveying texture, flavour or consistency, are still regarded as **food additives**, and these still need to be pre-cleared by the *Food and Drug Regulations*.[8] Ingredients for flavouring are also not considered food additives, and they do not need to be pre-cleared (even if they are artificial).

Let's take an example that we can all relate to, the Greens+® product by Genuine Health. It contains lecithin, various greens and fruit powders, chlorella, soy sprouts, stevia leaf powder, probiotic cultures, royal jelly, FOS, and various standardized herbal extracts. Per 8.5 g serving, it around 40 Calories, and the directions are to mix with water and drink. Without a doubt, this is a food product. Now, previously, adding ingredients that were chemically isolated (such as lecithin) or standardized herbal extracts, was considered unacceptable for food products in Canada. This is now changing. Because this is a powder drink mix, it is definitely considered a food. Whether it is a compliant food, is the difficult question. However, the NPN for this product will likely be eventually revoked, given its representation and format are that of a food.

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[7] Though it is equally probable that it is not so much their own perspective that is changing, but rather the industry becoming more aware of government mindset. I am unsure how much of the current thinking on foods has "changed" vs. how much we are learning for the first time simply because we as an industry are becoming more involved with the Food Directorate.

[8] Though the mechanism for this is changing this year, as I will discuss below.

In this example, take probiotics – as long as the probiotic ingredients are naturally part of the human intestinal flora, you could argue safe consumption in foods.[9] Standardized herbal extracts, even though their intended purpose is for conveying a health benefit, one could argue their presence in various markets as food (e.g., dietary supplements). Keep in mind during all of this, that there really isn't a tight definition on what a "food" is, and also that there isn't a minimum dose definition for safe use, or a duration over which the ingredient was consumed. It leaves it wide open.

Self-Determination of Novelty Status

In my conversations with the Food Directorate, a salient topic was that of how an ingredient can be classified a food ingredient or not. To be clear, the Food Directorate is not in the business of creating a positive/negative list of acceptable food ingredients any time soon. The overwhelmingly vast majority of food products on the market do not undergo a novel food notification process or a review of their claims; they simply come to market.

The FD has conveyed to me that a manufacturer has the primary responsibility of producing a **self-determination**[10] if their product ingredients are acceptable food ingredients or not. There is no regulatory or legislative requirement for a manufacturer to bring their product to the FD for pre-market assessment,[11] unless of course it is genetically modified and it has changed the ingredient significantly. So, if for example a manufacturer believed, based on their own research of its market history and studied benefits, that L-carnitine was an acceptable food ingredient, they could rely on their own "self-determination" as confidence in bringing that product to market without undergoing a Temporary Market Authorization Letter (TMAL) or Novel Food Notification (NFN).[12] If they felt justified in their decision, they could simply come to market.

Now, food additives still have to be pre-cleared by the FD, and I'll touch on that below. But when it comes to ingredients that are added to a product for reasons other than preservation, texture, consistency or colour, there is now a wide interpretation as to what is considered a valid food ingredient.

Now, a manufacturer can still ask the FD for their opinion on the food status of their product, if they consider it novel. This may be especially useful for companies that desire a higher certainty in their product launches.[13]

After all, just because a manufacturer "thinks" their product is a compliant, doesn't make it so. Let's say a manufacturer launches a powder comprising standardized herbal extracts and rice protein, and they determine on their own that it is a compliant food (i.e., its ingredients have a safe history of use as food ingredients, however they rationalize it). They come to market, and then a competitor calls the CFIA and complains about the product not being a compliant food (in their opinion). If the situation was considered a substantial risk, the CFIA would likely contact

[9] You may not be able to call them "probiotics", but that is a different story.
[10] This is a term the FD has used with us recently.
[11] With the exception of certain types of food (e.g., infant formulas, truly novel foods, foods with food additives that are not pre-cleared).
[12] I will explain these two processes in detail below; for the time being, all you need to know is they are used differently, but both attempt to bring a non-compliant food into market compliance.
[13] Also please keep in mind that simply the fact that a food is "not novel", does not imply that the food is compliant with all other aspects of the *FDA&R*.

the FD, and the FD could undertake a review of the product to determine if the ingredients are acceptable food ingredients. This is all under their risk-based compliance/enforcement approach. The FD may even ask the manufacturer to submit a Novel Food Notification (NFN), providing their reasons for considering it a compliant food. Most likely, the CFIA would not require the product to be recalled on the market during such a process – at least, this is based on what we have been told by Health Canada. One of their guiding principles in the food-nhp interface issue, is to preserve market access as much as possible during any transition or academic debate, unless there is a strong potential for consumer harm identified early in the process.

Temporary Market Authorization Letters

A **Temporary Market Authorization** Letter (TMAL for short) is a term gaining popularity in the food and nhp world. Let me clarify what a TMAL is used for, and what it is not used for, because there is considerable confusion in the natural health industry about TMAL's.

The purpose of the TMAL is singular – to gather market data on products with certain kinds of ingredients, to determine if they are safe food ingredients over time. The overarching goal for government is to then make a regulatory decision or ammendment, after collecting such data. A product is only eligible for a TMAL if the FD is interested in learning more about any of its ingredients. In other words, a TMAL is a government tool, not an industry tool, and it is intended as an information gathering mechanism, allowing the FD to understand how certain non-compliant foods are consumed and sold in Canada. Right now, the FD only seems interested in studying three types of ingredients through the TMAL process: (1) added vitamins; (2) added minerals; and (3) added amino acids. So, if a product has one of these three types of ingredients, it is "eligible" for a TMAL, because the FD wants to study these ingredients on the market when they are added to foods. However, if a food product does not contain a vitamin, mineral or amino acid, the FD will not consider it eligible for a TMAL.[14]

A TMAL is <u>not</u> similar to an NPN, and it is not a licence of any kind. The only thing that a TMAL does, is it exempts a product from the *Food and Drugs Act* for novel food ingredients and food additives. And keep in mind that a TMAL is only temporary – for energy drinks they last five years, but for powders they only last two years (based on current practices, though it is entirely up to the discretion of the FD). It is a mechanism allowing the FD to study the product on the market, even though it is non-compliant.

Keep in mind something here – that vitamins, minerals and amino acids cannot be considered food additives according to the *Food and Drug Regulations*.[15] And right now, the FD is not considering vitamins, minerals and amino acids to be valid food ingredients – in the future, after this five year period, they may very well consider them food ingredients, but time will tell. Vitamins, minerals and amino acids are generally speaking the only "classes" of ingredients that the FD seems interested in gathering data on, though the FD can certainly identify unique situations/ingredients other than these (on a case by case basis).

[14] Caffeined Energy Drinks (CED's) such as Red Bull®, are an exception. This is a specific category of products that the FD is also interested in gathering data, the basic requirement being it has to have caffeine between 200 and 400 ppm, and it cannot have certain other ingredients (among other compositional requirements). Though keep in mind that CED's undergo the normal TMAL process as any other food product with added vitamins, minerals or amino acids.
[15] Section B.01.001.

So, if a product is classified as a food (based on the previous discussion, see above), a TMAL is only required if the food contains an ingredient for which additional in-market information is required prior to proceeding with a regulatory amendment. At present, vitamins, minerals and amino acids are the three classes of ingredients which the FD is requesting in-market information as a broad policy.

Now, a TMAL does not really "approve" health claims[16], though generally speaking health claims are not an impediment to the issuance of a TMAL.[17] A TMAL also does not automatically mean that the ingredients will be considered acceptable food ingredients after the TMAL expires – nor does it mean that its food additive ingredients will be considered acceptable food additives by the end of the TMAL. Further to this, the FD does not automatically notify TMAL holders if they should pursue NFN's or Food Additive Submission (FAS) while the TMAL is in effect – the FD considers it the responsibility of the TMAL holder to make that determination on their own, though I am led to believe that on occasion they may mention this.[18]

Also keep in mind, that if a manufacturer is selling a food product with a vitamin, mineral and/or amino acid added to it[19], they are required to undergo the TMAL process – it is not optional. There is no law that states that a manufacturer must do this, but if they don't do this then they are selling an illegal product. This is a special situation where the FD has made a decision regarding food ingredients, requiring TMAL's.

To summarize, if a food product is eligible for a TMAL because it has a vitamin, mineral or amino acid, even if it has all kinds of other ingredients, the FD will issue a TMAL. But this does not mean the FD "approves" the food and considers it compliant now. It just means they are watching it on the market, under the provision of the TMAL.

It must be stressed that even though the TMAL process has been defined in the *Food and Drug Regulations* for quite some time, it was never really used until recently. Only a few were issued prior to 2012. The FD has realized that the TMAL process has the potential to be used as a mechanism for studying new trends in a few categories of products, i.e. those with added vitamins, minerals or amino acids. So we're all new to TMAL's.

Novel Food Notifications

Now, if a manufacturer wants to sell a food product in Canada, but this product does not have a vitamin, mineral or amino acid (and it is also not a CED), they can submit what is called a **Novel Food Notification** (NFN) to the FD, if they want a decision as to whether or not their product is anovel (i.e., if the FD objects to the use of a given ingredient, process or food). They don't have to provide extensive data in the initial submission, and at most the process could take up to 135 days.[20] A **novel food** is really only "novel" until the FD finishes this process – the

[16] With the exception of CED's, which have some rules regarding claims.
[17] Except of course for *Schedule A* diseases (e.g., cancer, depression).
[18] They are not required to mention this, it should be noted.
[19] Excluding, of course, mandatory fortification defined by the *Food and Drug Regulations* in a few rare instances, such as flour or milk.
[20] I.e., not including days when the applicant is gathering data in response

end result is their decision if they consider the food either compliant or non-compliant, i.e. it doesn't remain a "novel food" after that process.[21]

So, if a manufacturer felt they needed the extra confidence in launching a product, that it is a compliant food (i.e., its ingredients are valid food ingredients), they can undergo the NFN process and get a decision. There are no fees associated with filing an NFN, and it does not take a long period of time. However, the NFN process is not mandatory – and a manufacturer can simply rely on their own self-determination rather than undergo the NFN process.

Historically, NFN's have been used for a small number of product categories. You may recall that the NFN process was originally intended for genetically modified foods, and not really for foods that have an uncertain "food status". Most NFN's have therefore been issued to products sold by large food manufacturers, such as margarine with added sterols. Even then, only a handful have been issued per year. This isn't because there is a high fail rate – it is because it is not taken advantage of very often. This may also help explain the FD's opinion on novel foods – that they really are relying on the industry to make self-determinations rather than their involvement through NFN's.

If the FD reviews an NFN and they do not object to the ingredients/product as a food, they will issue a **Letter of No Objection** (LNO) to the applicant. This is not a licence, but it can be used as an aid to show retailers and importers (and competitors) that the product is indeed compliant. Keep in mind that this does not imply that the product is compliant against other aspects of the *FDA&R*, but it does provide some peace of mind to the manufacturer that the ingredients are acceptable food ingredients.

If the FD reviews an NFN and they do not consider it to be safe for consumption as a food, the product would then have to be reformulated and likely recalled off the market. However, it is my understanding that the CFIA and FD are of the same mindset, that the definition of "safe history of use as a food" is quite broad, and that this would not be expected to happen often.

Now, there is something that has to be said here. If a manufacturer launches a product and there really isn't a safe history of use for any of its ingredients (and they are traditionally not food ingredients) – then technically the NFN is mandatory, and it is a pre-market requirement. In other words, before they are allowed to sell the product, they are required to undergo the NFN to obtain an LNO before they can sell. But, really, what is the definition of "safe history of use" – and if the FD is allowing manufacturers to make this determination on their own, then naturally there will be considerable leeway here it CFIA responded to a complaint. Of course, time will tell, but this is what Health Canada is communicating to stakeholders right now.

Food Additives

Historically, the approval of a new food additive has taken years – stevia extract, for example, has taken some 3 to 4 years, and this November it is scheduled for approval. However, this is also changing. Thanks for Bill C-38 which passed through Parliament earlier this year, the FD now has a different tool for approving food additives (and extending the uses of listed additives), through what is being called a **Market Authorization (MA) Tool**. Before, food additives had to be listed in the tables in Division 16 of the *Food and Drug Regulations* before you could use them in a

[21] Also remember that there are three types of novelty when it comes to food – nove process of manufacturing, genetic modification, and safe history of use as a food. For this discussion, we are only interested in the last type of novelty.

product. With Bill C-38, they are building the approval process outside of the *Food and Drug Regulations* – the MA Tool is sanctioned by the *Regulations*, and so adding new food additives will not require a regulatory amendment (which is what historically has taken so long with food additives).

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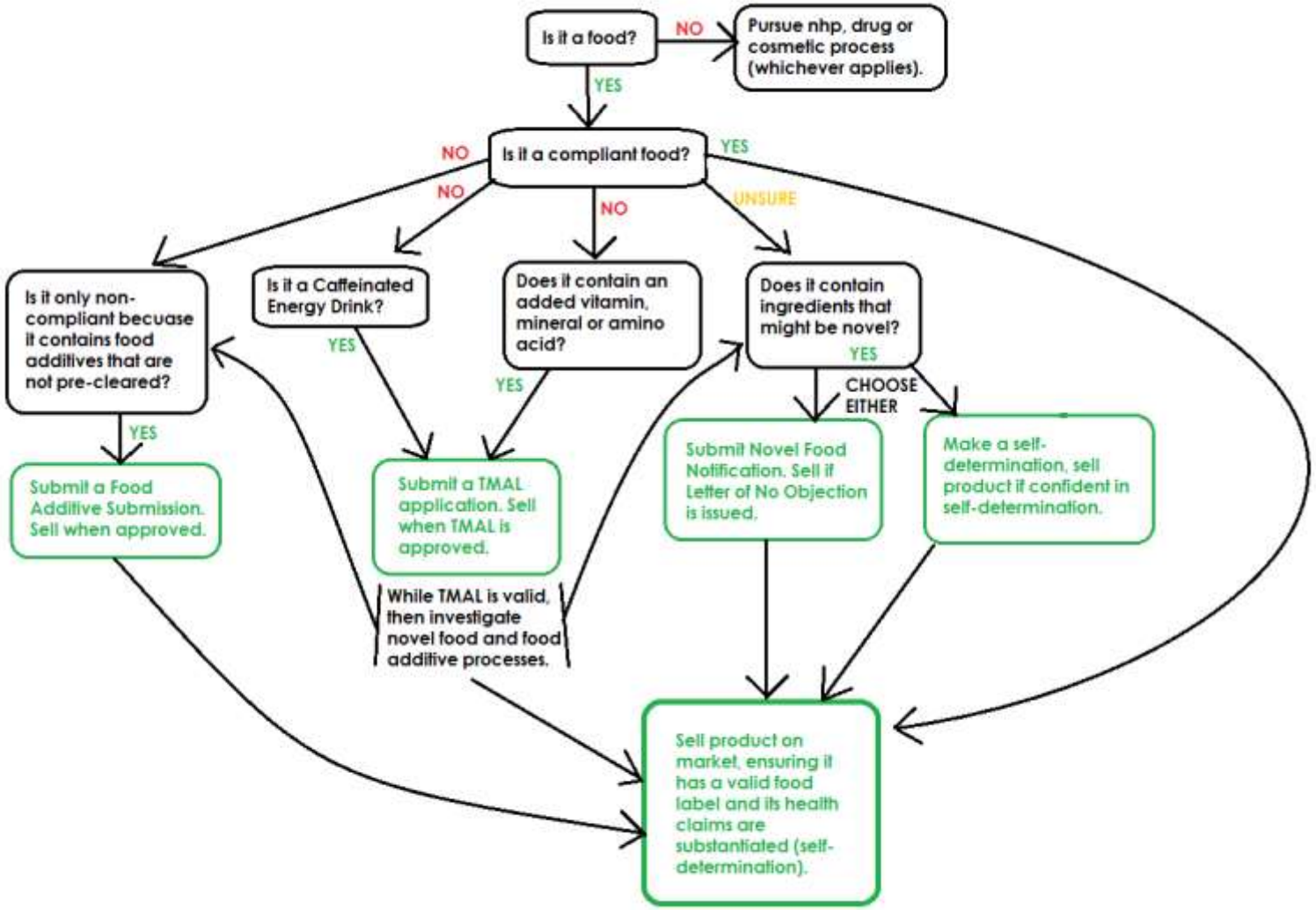
Flowchart of TMAL Elibigility

The following flow chart summarizes the processes for the regulation of food products in Canada.



Health Claims on Food

Historically, food manufacturers have been weary of having health claims on food labels, and also historically the CFIA has policed label claims they felt were unsubstantiated. However, this is changing.[22]

Now, technically, there are some claims that trigger the definition of a drug – what we call **drug claims**, because they are said "trigger" the definition of a drug. Drug claims are products that claim to:

> *(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or*
> *(b) restoring, correcting or modifying organic functions in human beings or animals.*[23]

These are sometimes called "health claims", and they convey a health benefit by taking a product. In other words, taking the product is expected to convey a specific health benefit.

However, **function claims** are not considered to be drug claims. According to the CFIA, "food provides energy and the building blocks needed for growth, development, and the maintenance of life and health" and that "function claims relate to the specific beneficial effects that the consumption of a food or a constituent of a food (nutrient or other compound) has on the normal functions or biological activities of the body"[24]. Also, the CFIA has published this statement, that "a function claim about the physiological effects of food or food constituents must not refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or of their symptoms" and that "claims about restoring or correcting abnormal functions of the body or modifying body functions beyond the normal physiological effects of good are considered to be drug claims" and "would require a pre-market review".[25]

Function claims are not drug claims, and they do not require pre-market approval for foods. For example, "antioxidant" or "helps in the digestion of food" or "lowers the glycemic load of a meal" would be function claims that do not trigger the definition of a drug. As long as these claims are truthful and not misleading, foods can make these claims freely and without pre-market assessment. While this has always been the case with food, few manufacturers have taken advantage of this avenue for food. Now, function claims are indeed limited, and they cannot convey a restorative or corrective effect (e.g., lowering elevated cholesterol thereby promoting cardiovascular health"), but they can definitely describe the normal physiological effect of the food.

Interestingly, with the CFIA and FD broadening their definition of what is now permitted as food ingredients, one can make an argument for any ingredient in a food product as having a physiological effect in the body. For example, a standardized herbal extract in a beverage that

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[22] All claims, including function claims, still have to have substantiation behind them before coming to market, however. This is unchanged. All claims must be based on evidence.
[23] *Food and Drugs Act*, Section 2.
[24] http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.shtml#a8_5
[25] *Ibid.*

stimulates immune parameters – so long as it doesn't mention any diseases or abnormal states – would be permitted to have this kind of function claim without any pre-market approval.

For a food to make a drug claim, we would have to make a legislative amendment to the *Food and Drug Regulations* exempting that claim from the definition of a drug. However, staying away from drug claims still leaves manufacturers with some room for truthful advertising – conveying promotional messages about their products without crossing the line (the drug line).

If the ingredient making the claim is a known nutrient (i.e., vitamin or mineral, protein, fat, DHA, ARA, or carbohydrate), if that nutrient has an established RDI then you need at least 5% of that RDI to make a claim. The CFIA also has a list of published acceptable (i.e., not objectionable) function claims for nutrients – called **nutrient function claims** – on their website, such as protein helping build strong muscles and antibodies. They also list three ingredients (psyllium, oat bran, and green tea) with function claims they do not object to. But these are not the only function claims out there – and this list is not intended to be a proscriptive list; rather, they are just a few examples of what can be used. The FD and CFIA have not been in the business of publishing positive/negative lists of claims that they do not object to.[26]

Also keep in mind that function claims are neither "approved" nor "not approved" by the FD. The FD does not have the jurisdiction to approve or deny them. If they "object" to a function claim, it is because they do not consider it to be a function claim, or else they do not consider the available evidence to support the claim. In the latter case, this becomes an issue of truthfulness – i.e., the available evidence doesn't support the claim. However, there are no published standards of evidence for function claims, and "truthfulness" is therefore open to a wide variety of academic opinions.

In this way, "structure function claims" in the US definition are very similar to Canadian "function claims".[27] But keep in mind that Canadian function claims on food cannot imply a restorative or corrective function – they can only describe an effect in the body.

In reality, a "health claim" is a difficult definition. The NHPD is now starting to call drug claims "health claims", and so in this sense function claims are not health claims (i.e., drug claims).

The take-home message is that function claims are allowed on food products, and they do not require pre-market assessment. If a manufacturer desires, they can submit their claims to the FD health claims assessment division to get their opinion, but my impression is that the FD does not want to be in the business of reviewing function claims, and they would rather have manufacturers make self-determinations if their claims are (1) valid function claims; and (2) supported by enough evidence (i.e., they are truthful).

Standards of Evidence for Function Claims

This is where we are in foreign territory. "Health claims" (i.e., drug claims) have defined standards of evidence for food, and these require pre-market assessment. But function claims do not have published standards of evidence. Reasonably speaking, it should be assumed that some kind of human data exists to make a function claim for an ingredient.

[26] However, the FD is considering publishing such a list in the future.
[27] But note that nhp structure-function claims are very different, because these always need to have a **health context**, even if it means just adding "for the maintenance of good health" at the end. A health context makes it a drug claim.

Note well that with foods, function claims should specifically mention which food ingredient(s) is/are the basis of the claim.

Dose Directions and Warnings on Food

This is also something that the CFIA and FD had previous opinions on, which are changing. Previously, having warnings and dose directions on food was thought to trigger a drug definition, and were not appropriate for products that could be consumed *ad libitum*. However, the FD and CFIA are modifying this approach during this transition. A food product can now have dose directions and even warnings, while still classifying it as a food. (Compare this with a bottle of cayenne pepper which has a warning not to get it in your eyes, or warnings added to CED's about pregnancy.)

Final Thoughts On Health Claims

Health claims (or just "claims") for foods has been perceived as forbidden in the past by most manufacturers, but really for ungrounded reasons. I think most of this has stemmed from a confusion between drug claims and function claims. Also keep in mind that the FD is still a few years away on having a more efficient system for analyzing claims (including health claims), and this new system will replace their current approach. But it's at least a few years away, according to the FD. (Incidentally, this is also another reason why TMAL's are being issued for two to five years, to give them time to actually develop this system.) Meanwhile, what's been communicated to our company by the FD, is that between now and then we will see a great relaxation of claims on food – not to mention what is allowed in food as food ingredients.[28]

[28] The modernization of food regulation is underway, and of course this last paragraph is more speculation than anything else. We shall see it when we see it.

Where We Go From Here

If a food contains a vitamin, mineral or amino acid, a TMAL is required (mandatory) to be issued before you can sell the product. However, keep in mind that the end of UPLAR (February 4, 2013) marks the end of the grace period for products without TMAL's – and so you are advised to submit a TMAL as soon as possible if you are required to do so.

If you suspect your product may be non-compliant because it contains certain ingredients that may or may not be acceptable as food ingredients (e.g., creatine added to a protein bar), you have two options – (1) make a self-determination if it is a compliant food; or (2) ask the FD for advice. Now, right out of the gate you could submit a Novel Food Notification (NFN), and you would know within 135 days or so if they object to anything (compositionally speaking). But the NFN division does not have the capacity as the TMAL division – and the FD is suggesting that if a manufacturer wants to determine if their product is a compliant food in terms of its food ingredients, that they could submit a TMAL anyways (even if they know they are not eligible for one). The FD would then issue a letter saying the product does not require a TMAL, and the same letter would also inform the applicant if it is a compliant food or not. The FD has suggested this mechanism as a quick way for manufacturers to gauge the composition of their product. Otherwise, an NFN can be submitted, but it may take longer.

So which ingredients will be acceptable as food ingredients? In my opinion, that is going to take some time to "feel out" with Health Canada. However, we would encourage companies to submit TMAL's for products that could be non-compliant in terms of its food ingredients.[29] At least for a while, until we become more familiar with how the FD is thinking.

If you try for a TMAL and the FD issues you a letter indicating that the product does not require a TMAL, they will also tell you if the ingredients are acceptable (i.e., not objectionable) food ingredients. You can then use this letter to defend any questions from the CFIA or competitors.

Worse case scenario, if a manufacturer makes a self-determination on their product, creates a compliant food label, and launches the product – if the a competitor complains about the product, the CFIA will involve the FD at that point, and the product will be analyzed for its novelty. However, keep in mind that the CFIA is not in the business of looking at ingredient lists – they are paying more attention to accurate Nutrition Facts panels and bilingual requirements, and even then they are mostly investigating due to competitor complaints. In other words, the CFIA does not assess compliance of novelty; rather, only with other requirements of the *FDA&R*.

The CFIA is also working on a modernization of their current enforcement policies, and which should reflect what I've been writing here as well.

[29] Excluding, of course, products that contain vitamins, minerals and/or amino acids, which we know are non-compliant and require TMAL's.