

# Overview

A key mandate of the Canadian Centre for Agri-Food Research in Health and Medicine (CCARM) is to provide information to the public regarding functional foods, nutraceuticals, and natural health products. The goal of these pages is to help members of the public make informed choices when it comes to selecting a supplemental health product, if that is the route they want to take in terms of improving their health. There are many products available that claim to improve the health of those who take these products, but it is difficult to tell which of these products actually provide the benefits they claim.

Natural remedies have been used since prehistoric times, however, it has only been over the last hundred years that scientific evaluation has been possible. As a result, there are numerous products that are sold on the basis that their original use is valid even in the absence of any scientific validation. While certain herbal remedies contain potent pharmacologically-active compounds, with willow bark being a good example since it contains a pain killer that was used to develop Aspirin, the vast majority of these remedies have not been examined to the same extent. Consequently, their active ingredients, if they have any, are unknown. Furthermore, they have not undergone the same rigorous testing as drugs that are prescribed by a doctor. Thus, there are a number of reasons why they might not be as effective as their claims might suggest. But what should someone who wants a natural product look for? And how do you know which products have been tested to make sure they are both effective and safe? To help answer these important questions, we will go over some of the definitions that are needed to understand the terminology used for describing natural health products, and then identify the characteristics that must be provided to determine whether a product will provide the benefits it claims.

A *Functional Food* is generally defined as a food product eaten

as part of your regular diet that has the ability to provide health benefits or reduce chronic disease through components that supply you with more than simple nutrition.

A *Nutraceutical* is an item that has been isolated or purified from foods and when consumed has a beneficial effect on health. A nutraceutical does not have to be a pure compound but can be a mixture of active and inactive compounds. However, it is usual to expect that the nutraceutical will be more concentrated than the food it is prepared from and should therefore be more active ingredients than the food.

The term *Natural Health Product* generally applies to products such as herbal medicines, homeopathic medicines, traditional medicines (Chinese, Indigenous) and other substances that are expected to improve health but can be sold over-the-counter. It is generally assumed they have fewer side effects than drugs.

*Regulation:* Although all countries have some sort of government oversight of food and drugs, the regulatory agencies with jurisdiction for functional foods, nutraceuticals and natural health products in North America are Health Canada (specifically the Natural and Non-Prescription Health Products Directorate) and the U.S. Food and Drug Administration, and Europe has the European Food Safety Authority/Committee on Herbal Medicinal Products. The role of these agencies is to ensure the products sold in these locations are safe to consume and that the claims about improving health or protecting against disease are valid. However, a number of products do not get evaluated because they are considered traditional or they were in use before the regulatory agencies became operational. While the intention may be to eventually review all products now being marketed, it is likely that many years will pass before this goal is achieved.

*Health Claims:* Health Canada has defined a health claim as

“any representation in labelling or advertising that states, suggests, or implies that a relationship exists between consumption of a food or an ingredient in the food and a person’s health” (May 17, 2016). Those claims that have been approved are provided on their website: <http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/asses-s-evalu/index-eng.php>. The allowed claims fall into two broad categories. A *Disease Reduction* claim can link consumption of an item to a reduction in disease risk. A *Function* claim applies to an item that is beneficial for a normal bodily function. It is important to note that the type of health claim allowed in other countries can differ substantially from what is possible in Canada. It is therefore important to make sure that you are aware of the regulations that apply to the country you live in.

To be sold in Canada, all Natural Health Products must be licensed by Health Canada. As well, the products must be manufactured in a facility that adheres to Good Manufacturing Practice (GMP). Finally, they must provide evidence of safety and efficacy. While all products should have the Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) clearly visible on the label, and should have been made in a GMP-certified plant, it is often difficult to determine if there is evidence to support the claims made by the manufacturer regarding the health benefits. Some of this information may be available in the Health Canada monograph for the item, but the monographs are generally supplied by the manufacturer. For this reason, the only way to determine if the product will fulfill the claims associated with it is to see the results of its testing (by the manufacturer or an independent laboratory) reported in a peer-reviewed scientific journal.

Specific aspects of this testing include disclosure of the contents of the product, including both the active and non-active ingredients. A statement of purity should also be

provided, and a standard method of analysis described that is used to ensure each container of product is identical in its composition. The effective dose should be provided, since too little will not give you the benefits and too much may be harmful. Both product safety and its possible side effects should also have been investigated. While it is generally assumed that a natural product is safer than a drug, the active ingredient or certain impurities in the preparation may result in interactions with drugs you are taking and/or foods you are eating. Finally, while much of this information could be obtained by preclinical studies in animals, the results of tests in humans (clinical trial) should be presented as verification that you should be able to expect a health benefit. Not all products will have been examined to the degree expected, but the availability of most of the information indicated here is essential in order to be certain the product will work as advertised.