General comparison of health claims with regards to food and supplement legislation frameworks in Europe, the United States, and Canada

Nigel Baldwin and Theresa Poon

In the EU, it is important point to note that, while supplements have their own legislation for basic presentation, vitamins and minerals lists, warning labels and the like, they are fundamentally considered to be foods. This means that the same legislation that applies to the manufacture, recommended daily allowances, nutritional labeling, and packaging font sizes in foods also applies to supplements. For example, Regulation 1924/2006 on health and nutrition claims on foods (1) applies to supplements, just as it does to foods.

Much has been written about the nutrition and health claims regulation. Essentially there are three types of claims.

1. Article 13-related claims are about maintenance or support of healthy physiology or psychological function.
   a. Article 13.3 applies to grandfathered products.
   b. Article 13.5 applies to new full submissions.
2. Article 14.1 (a)-related claims refer to disease risk (factor) reduction.
3. Article 14.1(b)-related claims refer specifically to children’s development and health (a general population claim that also includes children is Article 13 in most cases).

Now that the dust has settled and the “grandfathering” of existing claims is more or less complete, we are left with a submission process and a positive list of health claims. To get on the list, you make a dossier and submit via a Member State. Then the European Food Safety Authority (EFSA) reviews and delivers an opinion. This is followed by a one-month public comment period before the dossier is either refused or approved; in the latter case the dossier becomes an approved claim that is adopted into EU legislation and added to the Commission database. In theory, you can withdraw before your claim is refused, but legally you have to do this before the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) reaches an opinion, and often you do not know whether the decision is positive or negative until its adoption.

If you want to see the EFSA claims “Register” for yourself and read things in more detail, review the Commission’s web page (2); and for more details on EFSA’s approach, have a look at EFSA’s very informative site (3).

Reference to general, nonspecific health claims is acceptable only if used in conjunction with an authorized health claim. Also, endorsement by charities and medical doctors is severely restricted. To avoid misleading consumers, food business operators have the responsibility to demonstrate the link between the general, nonspecific benefits of the food and...
The success rate for approval of specific and general health claims has not been very high but is improving as dossiers of higher quality have been submitted and as the guidance has improved. Currently, claims that are “on hold” include claims on caffeine, because EFSA has been asked to review the safety implications of approving them, and on “botanicals” (i.e., “food herbs”), because the Commission and Member States are still trying to decide and agree on an alternative (if there is one) to the currently pure scientific review process to allow for traditional use to be taken into account. In the meantime, claims are also subject to standard EU claims law, which means that, on a case-by-case basis, they must not be judged to mislead the consumer to a material degree.

In the United States, a “dietary supplement” is regulated separately from a food, but, for the most part, claims rules apply to both product categories. However, where the EU has Article 13.3 or 13.5 “health claims”, the United States has “structure/function claims”; and where the EU has Article 14.1 (a) disease risk (factor) reduction claims, the United States has disease (direct not factor) risk reduction health claims that are referred to as authorized/notified health claims or qualified health claims.

Structure/function claims generally do not need presubmission approval, apart from the requirement for notification to US Food and Drug Administration (FDA) within 30 days of first marketing of dietary supplements. FDA does not check the science of the claim (as that is the responsibility of the marketer, but FDA does check to ensure that the claim does not contravene medicines and other relevant consumer legislation). Structure/function claims must be based on “competent and reliable scientific evidence” and must:
1. Describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, or

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### TABLE 1. Examples of European Union health claims under Regulation (EC) No 1924/2006

<table>
<thead>
<tr>
<th>Article</th>
<th>Claim</th>
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<tbody>
<tr>
<td>Article 13.1</td>
<td>Beta-glucans contribute to the maintenance of normal blood cholesterol levels.</td>
</tr>
<tr>
<td>Article 13.5 (proprietary)</td>
<td>Water-Soluble Tomato Concentrate (WSTC) I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Article 14.1a (disease risk factor reduction)</td>
<td>Barley beta-glucans have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Article 14.1b (children)</td>
<td>Docosahexaenoic acid (DHA) maternal intake contributes to the normal brain development of the fetus and breastfed infants.</td>
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2. Characterize the action by which a nutrient or dietary ingredient maintains such structure or function.

The following disclaimer is required on dietary supplements that bear structure/function claims: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

For more information on structure function claims, for both dietary supplements and foods, FDA offers an excellent webpage (4).

Health claims that are authorized by the FDA under the Nutritional Labeling and Education Act (NLEA) or notified to the FDA under Food and Drug Administration Modernization Act (FDAMA) must demonstrate by submission to FDA that the level of scientific substantiation meets the standard of “significant scientific agreement” (SSA). Further information is available on the FDA website (5). An example of an authorized health claim is “Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke” (6).

Qualified health claims are those for which the totality of scientific evidence falls short of the SSA standard but that are supported by credible scientific evidence; thus, qualifying language is used to convey to the consumer the level of scientific evidence in support of the health claim. Historically, qualified health claims have been of reduced value because of limited consumer understanding of claim wording. For example, “Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated-fat and low-cholesterol diet, and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat content” (7).

Overall, there has been a greater success rate for approval of health claims in the United States than in the EU.

For Canada, the situation regarding “health claims” is complicated by the fact that supplements are called “Natural Health Products” (NHPs), which are regulated more or less as medicines on a product-by-product basis via a licensing procedure. Again, there is a distinction between function claims (referred to as “nutrient function or other function claims”) and disease risk reduction claims. Disease risk reduction and therapeutic claims can be made on foods or NHPs. In addition, even stronger claims, such as diagnostic, prevention, and cure claims can be made for NHPs, as shown in Table 2. All health claims on NHPs require full submission and scientific review by the Natural Health Products Directorate of Health Canada. For more information on health claims for foods and NHPs, please see web pages for the Health Canada and the Natural Health Products Directorates (8,9).

Having reviewed the three jurisdictions, we can summarize the different approaches as follows:

1. For nondisease-related claims, the EU specifically approves generic claims based on ingredients, the
In summary I am, dare I say it, excited about the amount of work being undertaken to more accurately understand the vast number of stationary phases we currently have. With a better understanding we will be able to optimise our column selection strategies and at the very least make an informed choice as to which stationary phase to choose next after our favoured C18 has failed us. I am also pleased to see the continued trend, in the main, where the majority of new columns introduced are designed for specific applications such as proteins/peptides and other bio-molecules, PAHs and so forth and not just ‘me too’ phases clogging up an already congested column marketplace. I am slightly concerned about the knowledge which currently seems to being lost from method development groups as people rely on automation/modeling software and increases in efficiencies to solve all resolution problems. In addition, the current trend seems to be move away from method development groups and have a few skilled scientists working cross-functionally – whilst there are clear project based benefits to this approach I cannot help to think that in isolation certain skills will become a little esoteric and I for one always benefited from bouncing ideas off others. Contrary to how it may have come across I am a huge fan of high efficiency stationary phases and in particular how the (re-)introduction of core-shell particles has brought high efficiency separations to the mass market who cannot afford to upgrade all their conventional HPLC instruments. I am not some Luddite who shuns all advances, I am just a firm believer that we should all have at least a basic understanding of what is happening in our magical cream or black box, especially the column, and our role should not purely be to prepare samples and standards and place them into the vial rack. I sincerely hope we do not follow the well-trodden path of automotive industry whereby car engines are now shrouded in matt plastic covers and the days of actually seeing the internal workings, and therefore garnering a limited understanding and interest in how they work are a thing of the past. All I ask from column manufacturers is that selectivity is not forgotten – I am pleased to see that most manufacturers who supply the popular hybrid pH resistant, core-shell and sub 2µm stationary phases offer much more than a C18 or C8.

So, to answer my title question, do I think that the art of HPLC method development is dead? No, it’s fair to say that it’s not in the best shape but I still encounter enough chromatographers who share my passion and quest for knowledge and understanding of the subject to leave me feeling we’re not in dire straits just yet. Working as an analytical method development chemist is not purely a job title and you do not suddenly become well versed in the practice and understanding of method development by moving to the function. You learn from experience, trial and error and from ensuring you know enough about your subject to make these logical and pragmatic decisions which essentially all method development is. As to its condition in 5 or 10 years, let’s wait and see. I would like to finish with a request/challenge, next time you’re developing a method, or even just running you next routine analysis, have a look at your analyte structure and think if the C18 column you have in your hand is the best stationary phase for the separation… and… if in doubt….. ask.

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Health claims (cont. from page 396)

United States relies on self-regulation and enforcement discretion, and Canada has pre-approved generic claims for foods but not for product-based claims for supplements.

2. For the EU, applicant-exclusive claims based on proprietary data are permitted.

3. For disease-related claims, all three jurisdictions require premarket approval.

4. The EU is the only jurisdiction that assigns a specific class of health claims for children.

5. The United States is the only jurisdiction where claims supported by different levels of evidence are permitted.

Arguably, the EU appears to be most rigorous overall; the United States appears to allow for the most flexibility with respect to claims; and Canada may be somewhere in the middle. But since Canada’s NHPs are regulated as products, risk-benefit assessments are conducted and claims are approved on a case-by-case basis. This is something the EU definitely lacks because safety and efficacy assessments of new ingredients are completely separate regulatory processes. This deficit denies scientists, regulators, and consumers the ability to judge the product on the basis that it “is probably good for me” and is safe anyway.

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