

Background Summary and Charge to the Subcommittee

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA) (P.L. 103-417). This law amended the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 301 *et seq.*). Among other things, DSHEA defined the term “dietary supplement.” (See 21 U.S.C. § 321(ff)). Part of this statutory definition states that a “dietary supplement” is a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- ?? a vitamin
- ?? a mineral
- ?? an herb or other botanical
- ?? an amino acid
- ?? a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- ?? a concentrate, metabolite, constituent, extract, or combination of any ingredient named above.

The plain language of the Act and the statement of agreement that constitutes the legislative history of DSHEA do not provide an explanation of the scope or nature of the substances intended to be encompassed by the term “metabolite.” The ordinary, usual meaning of the term is of limited usefulness in identifying substances that may be encompassed by the term “metabolite.” For example, the term “metabolite” is defined differently by dictionaries and other reference sources:

- ?? A product of metabolism; a substance essential to the metabolism of a particular organism or a particular metabolic process [Merriam-Webster Dictionary]
- ?? Any substance produced by metabolism or by a metabolic process [The Cancer WEB Project, cancerweb.ncl.ac.uk]
- ?? Any product or substrate (foodstuff, intermediate, waste product) of metabolism especially catabolism [Stedman’s Medical Dictionary, www.stedmans.com]
- ?? a product of metabolism; a metabolic waste usually more or less toxic to the organism producing it; a product of one process that is essential to another such process in the same organism; a metabolic waste of one organism that is markedly toxic to another; a substance essential to the metabolism of a particular organism or to a particular metabolic process [FastHealth Interactive Healthcare, www.fasthealth.com]

These definitions appear to suggest that any substance present in an organism is a “metabolite.” The definitions, however, do not address when a particular substance is a metabolite of another dietary ingredient.¹ This fact is important to determining whether a substance is a dietary ingredient for purposes of identifying a “dietary supplement” under the Act. Therefore, in the context of substances that are produced and utilized in metabolic systems,

¹ For present purposes, “another dietary ingredient” means a vitamin, mineral, herb or other botanical, amino acid, or dietary substance for use by man to supplement the diet by increasing the total dietary intake.

the basic question at hand with respect to defining the term “metabolite” is whether it is possible to identify particular scientific criteria, principles, or conventions that enable a determination to be made about when a substance is or is not a metabolite of another dietary ingredient.