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Final Analysis

Legislative Service Commission

Sub. H.B. 381

123rd General Assembly
(As Passed by the General Assembly)

Reps. Perz, Gardner, Ford, Olman, Bateman, Britton, Corbin, Flannery, Hollister, Opfer, Padgett, Taylor, Winkler, Young, D. Miller, Mettler, Bender, O'Brien, Harris, Roberts, Jerse, Stevens, Hoops

Sens. Mumper, White, Latta, Watts, Gardner, Hagan

Effective date: *

ACT SUMMARY

- Codifies in Ohio law portions of the federal Food, Drug, and Cosmetic Act concerning dietary supplements.
- Specifies that a dietary supplement is treated the same as a food under Ohio law.
- Specifies that the Director of Agriculture has exclusive authority to administer and enforce the act's provisions.

CONTENT AND OPERATION

Intent

The act states that the intent of the statutes it enacts is to codify in Ohio law portions of the federal Dietary Supplements Health and Education Act of 1994 (Section 3).

* *The Legislative Service Commission had not received formal notification of the effective date at the time this analysis was prepared.*

Dietary supplements as food

The act specifies that a dietary supplement is to be treated as a food under the Ohio Pure Food and Drug Law and that the term "dietary supplement" has the same meaning as in the federal Food, Drug, and Cosmetic Act (R.C. 3715.80 and 3715.81).¹

Law not changed by the act specifies what constitutes a drug for the purposes of the Ohio Pure Food and Drug Law and the Pharmacy Law (R.C. 3715.01 and 4729.01, not in the act).² The act specifies that a dietary supplement is not to be considered a drug solely because the label or labeling of the dietary supplement contains a statement describing the supplement, as authorized by the act, or because the label contains a warning (R.C. 3715.84(D)). The act also specifies that a dietary supplement is not a "food additive" within the meaning used in the federal Food, Drug, and Cosmetic Act (R.C. 3715.86).

Administration

The act requires the Director of Agriculture to administer and enforce its provisions and any rules adopted under it (R.C. 3715.81). The act authorizes the Director to adopt rules regulating dietary supplements, but specifies that the rules may be no more restrictive than federal food, drug, and cosmetic regulations (R.C. 3715.82).

Adulterated products

Law not changed by the act specifies conditions under which a food is considered "adulterated" (R.C. 3715.59, not in the act). In addition to those conditions, the act adds that a dietary supplement is adulterated if it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in its labeling or, if there are no recommended or suggested conditions of use, under the ordinary conditions of use. If the Director finds or has cause to believe that a dietary supplement is adulterated, the Director must proceed as provided under continuing law for dealing with adulterated food.

¹ Under federal law, "dietary supplement" means a product, other than tobacco, intended to supplement the diet and includes any of the following: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance used by humans to increase total dietary intake, a concentrate, a metabolite, a constituent, an extract, or any combination of the previous ingredients.

² "Drug" means any article intended for the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or in animals and any article, other than food, intended to affect the structure or any function of a human or animal body.



The Director of Agriculture bears the burden of proving that a dietary supplement is adulterated. (R.C. 3715.83.)

Labeling of dietary supplements

Misbranding

Law not affected by the act provides that food is misbranded if its labeling is false or misleading in any particular or if the label fails to comply with other standards established in continuing law (R.C. 3715.60, not in the act). The act provides that a dietary supplement is not misbranded solely because the label or labeling contains a warning or a statement that characterizes the relationship of a nutrient or dietary ingredient to a disease or health-related condition if all of the following conditions are met:

- (1) The statement does one of the following:
 - (a) Claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of the disease in the United States;
 - (b) Describes the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body;
 - (c) Characterizes a documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function of the human body;
 - (d) Describes general well-being from consumption of a nutrient or dietary ingredient.
- (2) The manufacturer of the dietary supplement has substantiation that the statement is not false or misleading.
- (3) The label contains one of the following statements, prominently displayed and in boldface type:
 - (a) In the case of a product manufactured or sold in interstate commerce, "This statement has not been evaluated by the United States Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
 - (b) In the case of a product manufactured or sold only in Ohio, "This statement has not been evaluated by the Ohio Department of Agriculture. This product is not intended to diagnose, treat, cure, or prevent any disease."

(4) The manufacturer of the dietary supplement complies with the requirements of the federal Food, Drug, and Cosmetic Act.

The act also prohibits a dietary supplement label from claiming that the supplement is to be used to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

If the Director of Agriculture finds or has cause to believe that a dietary supplement is misbranded, the act requires the Director to proceed under the provisions of the Ohio Pure Food and Drug Law that prohibit misbranding. Under the act, the burden of proof to establish misbranding is on the Director. (R.C. 3715.84.)

Statements made related to sale of dietary supplements

Under the act, a person who offers dietary supplements for sale at retail, wholesale, or distribution may make the following statements without being subject to the laws that govern licensing of dietitians if the statements are consistent with the dietary supplement's label:

(1) Claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of the disease in the United States;

(2) Describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body;

(3) Characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function of the human body;

(4) Describe general well-being from the consumption of a nutrient or dietary ingredient. (R.C. 4759.10.)

Publications

Under the act, a publication, including a book chapter, article, or official abstract of a peer-reviewed scientific article prepared by the article's author or the editors of the publication in which the article is published, used in connection with the sale of dietary supplements to consumers, is not considered to be a part of the label of the dietary supplement if the publication meets all of the following criteria:

(1) The publication is reprinted in its entirety;

(2) The publication is not false or misleading;



(3) The publication does not promote a particular manufacturer or brand of dietary supplement;

(4) The publication is displayed or presented, alone or with other publications on the same subject matter, in a manner that presents a balanced view of the available scientific information on a dietary supplement;

(5) If the publication is displayed in a location where dietary supplements are offered for sale, the publication is physically separate from the dietary supplements;

(6) The publication does not have any other information affixed to it.

The act specifies that these requirements governing publications do not apply to or restrict the actions of a person who offers dietary supplements for sale at retail or wholesale in the sale of books or publications as part of the person's business.

Under the act, if the Director of Agriculture finds or has cause to believe that a publication used in the connection of the sale of a dietary supplement is actually a label and the label is false or misleading, the Director is required to proceed under the laws that prohibit misbranding food. Again the burden of proof under the act to establish misbranding is on the Director. (See above, "Misbranding.") (R.C. 3715.85.)

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	06-08-99	p. 785
Reported, H. Commerce & Labor	05-17-00	p. 1994
Passed House (94-1)	05-24-00	pp. 2097-2098
Reported, S. Agriculture	11-09-00	p. 2198
Passed Senate (33-0)	11-14-00	p. 2214

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