



## *Bill Analysis*

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*Legislative Service Commission*

### **H.B. 458**

123rd General Assembly  
(As Introduced)

**Reps. R. Miller, Barrett, D. Miller, Jerse, Allen, Beatty, Hartnett, Britton,  
Pringle, Gooding, Smith**

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#### **BILL SUMMARY**

- Defines "dietary supplement" for purposes of Ohio's pure food and drug law.
- Establishes standards for the labeling and packaging of dietary supplements.
- Authorizes the Director of Agriculture to investigate complaints regarding false or misleading expiration dates for dietary supplements.
- Requires the Director to conduct random inspections of establishments where dietary supplements are manufactured, processed, or packed, or held for introduction into commerce.
- Requires manufacturers of dietary supplements in this state to register annually with the Director.
- Requires the Director to adopt rules concerning registration and inspections of establishments where dietary supplements are manufactured, processed, or packed, or held for introduction into commerce.
- Specifies that dietary supplements are subject to certain provisions of the pure food and drug law.

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## CONTENT AND OPERATION

### Definition of "dietary supplement"

(sec. 3715.01)

The Revised Code does not define the term "dietary supplement," nor does it specifically describe how dietary supplements are to be regulated. Federal law now specifically addresses this issue, but did not do so until 1994. Until that time, federal law was not clear on the legal status of dietary supplements. In the absence of clear legislative direction, the United States Food and Drug Administration (FDA) attempted to regulate dietary supplements as food, over-the-counter drugs, new drugs, and food additives. In 1994 Congress enacted the Dietary Supplement and Health Education Act, which established standards for the regulation of dietary supplements.<sup>1</sup> The act requires dietary supplements to be regulated as food, not as drugs or food additives, and specifies requirements for nutritional labeling and nutrient content claims.

The federal definition of dietary supplement is complex. First, the focus of the product must be on supplementing the diet. Second, the product must contain either a pure form or a "concentrate, metabolite, constituent, extract, or combination" of any of the following: (1) a vitamin, (2) a mineral, (3) an herb or other botanical, (4) an amino acid, or (5) a diet substance intended to supplement the human diet by increasing the total dietary intake. Third, the product must be for ingestion or, if not in the form of a tablet, capsule, or liquid, must not simulate a conventional food, not be represented as a conventional food, and not be represented for use as a sole item of a meal or diet. Fourth, tobacco and new drugs not sold as dietary supplements before 1994 are excluded.<sup>2</sup>

The bill specifies that, for the purposes of Ohio's pure food and drug law, the term "dietary supplement" has the same meaning as in the Dietary Supplement and Health Education Act of 1994.

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<sup>1</sup> 108 Stat. 4325 (P.L. 103-417).

<sup>2</sup> 21 U.S.C. 321 (ff).

## Packaging requirements

### Labeling

(secs. 3715.60 and 3715.601)

Current law lists the circumstances in which a food is misbranded. The bill specifies that a dietary supplement is misbranded in the same circumstances. In addition, under the bill, a dietary supplement is misbranded under Ohio's pure food and drug law if it is packaged for retail sale and does not include a label that displays all of the following information:

(1) A brief description of the purposes for which the dietary supplement may be consumed. The description is required to describe the benefits that may be derived from the dietary supplement as a whole and may not disproportionately describe the effects of a proportionately small or inactive ingredient in the dietary supplement. In addition, the description must comply with provisions governing label claims in the Dietary Supplement Health and Education Act and regulations adopted under the federal law. A manufacturer's substantiation of a statement for a dietary supplement must include published findings that have resulted from peer-reviewed scientific studies.

(2) An expiration date, including a month and year, on and after which a dietary supplement that is subjected to normal conditions of exposure will cease to conform with all of the characteristics normally associated with the dietary supplement and will cease to provide the benefits for which the dietary supplement is normally purchased;

(3) The name and telephone number of the manufacturer of the dietary supplement;

(4) A statement that warns "Keep this product out of reach of children";

(5) A statement that says "Ask a doctor about side effects or interactions with other substances that may occur when using this product";

(6) A statement that is prominently placed so that consumers are alerted to the package's tamper-resistant feature and the statement will be unaffected if the tamper-resistant feature of the package is breached or missing. The statement must warn consumers not to use the dietary supplement if the tamper-resistant feature is breached or missing.

Misbranding is a fourth degree misdemeanor for the first offense, and a second degree misdemeanor for each subsequent offense.

### **Tamper-resistant packaging**

(secs. 3715.59 and 3715.77)

Existing law lists the circumstances under which a food is considered adulterated. The bill specifies that dietary supplements are adulterated under the same circumstances. In addition, the bill requires that each dietary supplement packaged for retail sale be contained in a tamper-resistant package if the dietary supplement is accessible to the public while held for sale. The tamper-resistant package must have one or more indicators or barriers to entry that, if breached or missing, reasonably can be expected to provide visible evidence to consumers that tampering may have occurred. The package must be distinctive by design and incapable of being duplicated with commonly available materials or through commonly available processes. The package may involve an immediate container and closure system, a secondary container or carton system, or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature must be designed to, and is required to, remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

For dietary supplements that are two-piece, hard gelatin capsule products, a minimum of two tamper-resistant packaging features is required unless the capsules are sealed by tamper-resistant technology. For all other dietary supplements, including two-piece, hard gelatin capsules that are sealed by a tamper-resistant technology, a minimum of one tamper-resistant feature is required.

A dietary supplement that is not contained in tamper-resistant packaging is adulterated under the pure food and drug law.

### **Expiration dates**

(secs. 3715.521, 3715.55, 3715.601, 3715.602, and 3715.99)

Under the bill, a dietary supplement is "expired" if the expiration date required to be on the supplement's label has passed. The bill prohibits the sale, offering for sale, or delivery at retail or to a consumer of any dietary supplement after the expiration date required under the bill. A person who violates this prohibition is guilty of a minor misdemeanor.

The Director of Agriculture is authorized by the bill to investigate complaints to determine whether the expiration date for a dietary supplement, as determined by the manufacturer, processor, or packager, is false or misleading to consumers. If the Director finds, on reasonable cause, that the expiration date is

false or misleading, the Director is required to establish an expiration date after providing reasonable notice and the opportunity for a hearing in accordance with the Administrative Procedure Act (Revised Code Chapter 119.).

### **Duties of the Director of Agriculture**

(sec. 3715.701)

Under the bill, the Director of Agriculture or the Director's designee is required to conduct random, unannounced inspections during reasonable hours of factories, warehouses, or establishments in which dietary supplements are manufactured, processed, or packed, or held for introduction into commerce. The inspections are to be conducted for the following purposes:

- (1) To determine whether any of the provisions of the pure food and drug law are being violated;
- (2) To secure samples of any dietary supplement.

The Director must make or cause to be made examinations of the samples to determine whether the pure food and drug law is being violated.

### **Rule-making authority**

(sec. 3715.76)

The Director of Agriculture is required to adopt rules in accordance with the Administrative Procedure Act to do all of the following:

- (1) Establish a registration form to be used by a person who manufactures dietary supplements in Ohio;
- (2) Specify information that a person registering with the Director must provide on the registration form;
- (3) Establish a reasonable registration fee in an amount sufficient to pay for the actual and necessary expenses incurred by the Department of Agriculture in administering the registration requirement;
- (4) Establish any other requirements and procedures necessary to administer the inspection or registration requirements.

### **Registration of dietary supplement manufacturers**

(secs. 3715.75 and 3715.99)

The bill requires each person who manufactures dietary supplements in Ohio to register annually with the Director. The person is required to submit a registration form to the Director on or before January 1 of each year together with the appropriate registration fee and must provide all of the following information:

- (1) The person's name, address, and telephone number;
- (2) A description of the type and annual volume of dietary supplements the person manufactures;
- (3) The names and addresses of persons in this state who process, pack, or hold for introduction into commerce the dietary supplements the person manufactures;
- (4) Any additional information the Director requests on the form.

The bill provides that any person who violates the registration requirement is guilty of a minor misdemeanor on a first offense and a third degree misdemeanor on each subsequent offense.

**Application of certain provisions of the pure food and drug law to dietary supplements**

**Prohibitions**

(secs. 3715.52 and 3715.54)

Current law contains a number of prohibitions concerning adulterated or misbranded foods, drugs, devices, and cosmetics. The bill specifies that the following existing prohibitions also apply to dietary supplements:

- (1) The manufacture, sale, or delivery, holding, or offering for sale of adulterated or misbranded items;
- (2) The adulteration or misbranding of such items;
- (3) The receipt in commerce of an adulterated or misbranded item;
- (4) The refusal to permit entry or inspection, or to permit the taking of a sample, of an item in accordance with the pure food and drug law;
- (5) Giving a false guaranty or undertaking, unless the person relied on another's good faith guaranty or undertaking and provides that person's name and address;

(6) The alteration, mutilation, destruction, obliteration, or removal of the item's labeling, if the act is done while the item is held for sale and results in the item being misbranded;

(7) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules;

(8) Use by a person to the person's own advantage of information acquired pursuant to the pure food and drug law or unauthorized disclosure of the information if the information is a trade secret.

The bill further provides that an existing exemption from the penalties for the manufacture, sale, or receipt of an adulterated or misbranded article when a person receives the article in good faith after assurances in writing that the article is not adulterated or misbranded applies in the case of adulteration or misbranding of dietary supplements.

### **False advertising**

(sec. 3715.68)

Existing law provides that an advertisement of a food, drug, device, or cosmetic is false if it is false or misleading in any particular. The bill specifies that an advertisement of a dietary supplement is false under the same circumstances.

### **Reporting**

(sec. 3715.71)

Current law permits the Director of Agriculture or the State Board of Pharmacy to publish reports summarizing court orders rendered under the pure food and drug law and to distribute information regarding food, drugs, devices, and cosmetics that the Director or Board considers necessary in the interest of public health and consumer protection. The bill specifies that this authority includes dietary supplements.

### **Enforcement**

(secs. 3715.55, 3715.56, 3715.57, 3715.61, and 3715.62)

Existing law provides the Director of Agriculture broad authority when a food is adulterated, misbranded, expired, or exposed to contamination. This includes (1) tagging the item and seeking an order for condemnation from the

court, (2) notifying the Attorney General or a prosecuting attorney or city law director of a violation of the pure food and drug law, (3) proposing rules for adoption by the Public Health Council concerning the issuance of permits for the manufacture, processing, or packing of a class of food for a temporary period, and (4) proposing rules for adoption by the Public Health Council limiting the quantity of poisonous or harmful substances in food. The bill specifies that the Director's authority also applies in the case of adulteration, misbranding, expiration, or exposure to contamination of dietary supplements.

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## COMMENT

The Supremacy Clause of the United States Constitution assures that when federal and state jurisdictions adopt different substantive requirements, the federal requirements will prevail (U.S. Const. Art. 6, cl. 2). Neither the federal "Food, Drug, and Cosmetic Act" nor the "Dietary Supplements and Health Education Act of 1994" expressly preempt state regulation, but preemption may be inferred if the scheme of federal regulation is comprehensive or the federal interest is so dominant that the federal law will be assumed to preclude enforcement of state laws on the same subject. Even if Congress has not completely displaced state law in a specific area, state law is nullified to the extent that it actually conflicts with the federal law. (*Hillsborough County, FLA v. Automated Medical Labs* (1985) 105 S. Ct. 2371).

It is possible that a court could conclude that the increased regulation provided for in this bill conflicts with federal law, which moved away from such regulation by defining dietary supplements as food in the Dietary Supplement and Health Education Act of 1994, and is therefore preempted.

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## HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	09-28-99	p. 1228
H0458-I.123/jc		