HB 1191

Department of Legislative Services

Maryland General Assembly
2014 Session

FISCAL AND POLICY NOTE

House Bill 1191 (Delegate A. Kelly, *et al.*)
Health and Government Operations

Health - General - Genetically Engineered Food - Labeling Requirements

This bill requires, beginning July 1, 2015, that (1) raw and packaged foods produced with genetic engineering be labeled by the manufacturer as such; (2) a supplier label a container used for packaging, holding, or transporting raw or packaged foods produced with genetic engineering; and (3) a retailer label a shelf or bin containing raw or packaged foods produced with genetic engineering. The bill provides authority for the enforcement of the bill by the Attorney General and, under specified circumstances, by residents, and establishes several defenses and exemptions from enforcement for specified persons. The bill also establishes the purpose of the bill, states numerous findings of the General Assembly, and defines several terms. Finally, the bill requires the Department of Health and Mental Hygiene (DHMH) to adopt regulations to implement the bill.

Fiscal Summary

State Effect: General fund expenditures increase by $104,600 in FY 2016 for DHMH to hire one additional inspector beginning July 1, 2015, and for associated vehicle, equipment, and other operating expenses; expenditures may increase further if additional inspectors are needed. The Office of the Attorney General (OAG) can implement the bill with existing budgeted resources. Revenues are not affected.

(in dollars)	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Revenues	$0	$0	$0	$0	$0
GF Expenditure	0	104,600	81,900	85,500	89,300
Net Effect	$0	($104,600)	($81,900)	($85,500)	($89,300)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: Local health department workloads and/or expenditures increase to enforce the requirements of the bill and any future regulations with respect to retail food service facilities subject to health department jurisdiction.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

Labeling Requirements

Beginning July 1, 2015, all raw and packaged foods produced with genetic engineering must be labeled by the manufacturer, and contain one of the following statements: "genetically engineered"; "produced with genetic engineering"; or "partially produced with genetic engineering." The label must be clearly and conspicuously placed on the front or back of the package.

A supplier must label a container used for packaging, holding, or transporting raw or packaged foods produced with genetic engineering with the statement "this package contains food that has been genetically engineered."

A retailer must clearly and conspicuously label a shelf or bin containing raw or packaged foods produced with genetic engineering with the statement "this food has been genetically engineered."

Enforcement, Exemptions, and Defenses

Subject to specified exceptions, OAG may bring an action to enjoin any violation of the bill, and a resident may bring an action to enjoin a violation of the bill by a manufacturer or retailer (but not a supplier) after providing notice to OAG and the alleged violator and after waiting 60 days before bringing the action. If a judgment is entered in favor of a resident bringing an action, the court may award the resident costs and attorney fees but may not award monetary damages.

These enforcement provisions do not apply to a manufacturer, supplier, or retailer for failure to comply with the bill's labeling requirements if food produced through genetic engineering accounts for less than 0.9% of the total weight of the packaged food, or if the food has not been produced with the knowing or intentional use of genetic engineering as determined by an independent organization under specified procedures. A retailer is also exempt from enforcement unless the retailer is also a manufacturer or supplier, sells the

foods under a brand owned by the retailer, and knowingly and intentionally failed to meet the labeling requirements. Finally, the bill exempts from enforcement a farmer who is not a retailer or manufacturer.

The bill establishes as a defense that a retailer reasonably relied on either a disclosure in the bill of sale or invoice provided by the wholesaler or distributor stating whether the food is genetically engineered or on a lack of a disclosure in the bill of sale or invoice.

The bill states that raw or packaged foods produced with genetic engineering are deemed to have not been produced with the knowing or intentional use of genetic engineering if (1) the food is certified to be labeled, marketed, and offered for sale as organic under the Organic Foods Production Act of 1990; (2) a manufacturer or retailer has obtained a sworn statement from the person that sold the food to the manufacturer, retailer, or supplier stating that the food was not knowingly or intentionally genetically engineered or commingled with foods that may have been genetically engineered; or (3) an independent organization has determined that the food has not been knowingly or intentionally genetically engineered, or commingled with foods that may have been genetically engineered, by using specified sampling and testing procedures.

Purpose and Statements of Findings

The bill specifies that the purpose of the labeling requirements are to (1) promote food safety and protect public health by serving as a risk management tool to enable consumers, physicians, and scientists to identify unintended health effects resulting from the consumption of genetically engineered foods and by enabling consumers to avoid potential risks associated with genetically engineered foods; (2) create and protect nongenetically engineered food markets; (3) enable consumers to make informed purchasing decisions; and (4) provide consumers with data to make informed decisions for personal, religious, moral, cultural, or ethical reasons. The bill also includes 17 statements of findings of the General Assembly in support of labeling requirements for genetically modified foods.

Definitions

The bill defines the terms "genetic engineering" and "genetically engineered" as the process of altering the genetic material of food through one of eight specified *in vitro* acid techniques or specified methods of fusing cells beyond the taxonomic family that either overcome one of three specified barriers or are not techniques used in traditional breeding and selection.

"Packaged foods" is defined as any food offered for retail sale in the State that is subject to the Maryland Food, Drug, and Cosmetic Act but specifically excludes (1) raw food; (2) food served, sold, or provided ready to eat in any bake sale, restaurant, or cafeteria; (3) meat products, as defined in a specified provision of the Agriculture Article; and (4) poultry products, as defined in a specified provision of the Agriculture Article. "Raw foods" is defined as any food offered for retail sale in the State that is in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form before marketing but does not include meat or poultry products as defined in a specified provision of the Agriculture Article.

Current Law: Maryland law does not regulate genetically modified food. However, the Maryland Food, Drug, and Cosmetic Act contains several labeling requirements and prohibitions affecting several food items; vendors of food are also governed by other labeling requirements of the Health-General Article. DHMH's Office of Food Protection and Consumer Health Services is responsible for assuring that all foods processed, prepared, stored, distributed, and served at both the retail and wholesale levels throughout the State are safe, wholesome, free of adulterants, and properly packaged and labeled.

Background: Food labeling is primarily regulated under the federal Food, Drug, and Cosmetic Act (FDCA). FDCA generally prohibits labeling that is false or misleading. According to the U.S. Food and Drug Administration (FDA), labeling is misleading if it fails to reveal "material" facts – information that is material in light of statements made or suggested on the label, or that is material with respect to consequences that may result from the use of the food.

According to FDA, genetically engineered foods have been in the food supply since the early 1990s. In 1992, FDA issued draft guidance on the labeling of genetically engineered foods in order to advise manufacturers on avoiding misleading statements voluntarily made on labels about genetically engineered foods. The guidance did not establish labeling standards or require labeling of genetically engineered foods, and further stated that there was no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way.

Several times in the 1990s – the most recent time being in 1999 – FDA solicited comments from the public about the labeling of genetically engineered foods. According to FDA, most of the comments requested mandatory disclosure of the fact that the food was bioengineered, but the comments did not provide data or other information regarding consequences to consumers from eating such foods or any other basis for FDA to find that such a disclosure was a material fact. Currently, FDA advises that it neither supports genetically engineered plants based on their perceived benefits nor opposes them based on their perceived risks. Instead, FDA recognizes that diverse views exist among food manufacturers, the agricultural industry, and the public. The most recently issued FDA

guidance document to manufacturers seeking to voluntarily label genetically engineered foods was released in 2001.

According to the Center for Food Safety, 61 countries have established laws requiring labeling of genetically modified foods, and nearly one-half of the states considered legislation in 2013 to establish labeling standards for genetically modified foods.

In 2013, Connecticut became the first state to enact a law requiring the labeling of genetically engineered foods, although the labeling requirements only take effect on the condition that four other northeastern states consisting of at least 20 million people also enact similar laws. Subsequently, Maine enacted a similar law, also contingent on the passage of similar laws in other states. Several other states had previously enacted more limited labeling provisions, such as the mandatory labeling of genetically engineered fish and shellfish, voluntary labeling of food products generally, and restrictions on the labeling of foods as organic if the foods are genetically modified. In 2012, California's Proposition 37, which would have generally required the labeling of genetically engineered foods, narrowly failed.

State Expenditures: General fund expenditures increase by $104,564 in fiscal 2016, which accounts for the July 1, 2015 effective date for the bill's labeling requirements, and by more than $81,949 annually thereafter, for DHMH to hire an additional inspector and to procure a car, mobile phone, equipment, and supplies for the inspector. DHMH advises that an inspector is needed to provide assistance to OAG in handling complaints and to otherwise enforce the bill. The estimate includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

	FY 2016
Position	1
Salary and Fringe Benefits	$71,046
Start-up and Operating Expenses	33,518
Total DHMH Expenditures	**$104,564**

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses. This estimate assumes that enforcement of the bill is conducted on a complaint-only basis, as discussed below. It is anticipated that the additional inspector position is dedicated exclusively to assisting OAG in enforcing the bill, including cases referred by residents, as authorized by the bill.

The estimate does not account for expenditures associated with additional inspector positions, which are needed if DHMH is to provide proactive and ongoing inspections of manufacturers, suppliers, and retailers to ensure full compliance with the bill. DHMH

advises that a total of three inspector positions are needed if the department is to provide such inspections. DHMH is required by the bill to adopt regulations to implement the bill's requirements and, depending on the content of the future regulations and the manner in which it decides to enforce the bill, general fund expenditures may increase, potentially by more than $225,000 annually, for DHMH to add three inspector positions, rather than one, which includes automobile, equipment, and ongoing operating costs associated with the positions.

Small Business Effect: Small business food manufacturers, suppliers, and retailers may incur a meaningful increase in costs to comply with the bill. These small businesses must ensure that the bill's labeling requirements are met, which may consist of redesigning packages, affixing labels, procuring signs or placards, or other such costs. Costs may be greatest for manufacturers, which may face the most difficulty in redesigning packaging and producing separate packaging for Maryland, and because suppliers are not subject to actions for injunctive relief authorized by the bill and retailers are subject to numerous exceptions. Additionally, small businesses engaged in food service generally may be indirectly impacted to the extent that a significant number of out-of-state manufacturers or suppliers choose not to distribute products into Maryland; it is unclear whether this may occur.

Additional Information

Prior Introductions: None.

Cross File: SB 778 (Senator Montgomery, *et al.*) - Education, Health, and Environmental Affairs.

Information Source(s): Office of the Attorney General, Maryland Department of Agriculture, Department of Health and Mental Hygiene, Judiciary (Administrative Office of the Courts), Center for Food Safety, U.S. Food and Drug Administration, Department of Legislative Services

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