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White paper on Washington State Initiative 522 (I-522):

Labeling of Foods Containing Genetically Modified Ingredients

October 2013

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The Washington State Academy of Sciences (WSAS) is an organization of Washington State's leading scientists and engineers dedicated to serving the state with scientific counsel. Formed as a working academy, not an honorary society, WSAS is modeled on the National Research Council. Its mission is two-fold:

> To provide expert scientific and engineering analysis to inform public policy making in Washington State, and
>
> To increase the role and visibility of science in the state.

WSAS was formed in response to authorizing legislation signed by Governor Gregoire in 2005. Its 12-member Founding Board of Directors was recommended to the governor by the presidents of Washington State University and the University of Washington, and duly appointed by the governor. In April 2007, WSAS was constituted by the Secretary of State as a private, independent 501(c)(3).

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White Paper on Washington State Initiative 522 (I-522):

Labeling of Foods Containing Genetically Modified Ingredients

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Preface

The Washington State Academy of Sciences (WSAS) was created by the State Legislature to provide unbiased scientific analyses on issues especially important and relevant to the State of Washington.

In March of 2013, a letter was sent to Dr. Robert Bates, Executive Director of the WSAS, by the leadership of state legislative committees dealing with health and agriculture, water, and natural resources, requesting that a white paper be drafted analyzing some of the issues behind Initiative 522, the Initiative that would require labeling all foods that include ingredients from genetically modified plants or animals (GM). This Initiative will be on the ballot in November 2013. Further, the legislators requested that this paper provide the background information that would assist the legislature in understanding the implications should I-522 pass. They asked a number of questions relating to the Initiative. These questions frame the text of this report.

In response to this letter, a Statement of Task (SOT) was drawn up by members of the WSAS that asked specific questions relating to the (1) Definition of Genetically Modified Organisms (GMOs) and their relevance in agriculture today, (2) Nutritional aspects of GMOs, (3) Safety of GMOs, (4) Policy and trade implications, and (5) Costs of regulation and enforcement.

Following approval of the SOT by the state legislative committees that had requested the report, a provisional committee of six experts was formed to address the questions regarding regulation and enforcement of labeling of GMOs. Following an internal review of the proposed committee members for any conflicts of interest that could influence their evaluation of the science addressing the SOT, their names and affiliations were posted on the WSAS web-site and comments were invited from the public. Because no comments were received, the SOT and provisional committee were declared permanent.

The committee members with their affiliations are: Dr. Thomas Marsh (Washington State University), Co-chair; Dr. Eugene Nester (University of Washington); Co-chair; Dr. Janet Beary (Washington State University); Dr. Dustin Pendell (Colorado State University); Dr. B.W. Poovaiah (Washington State University); and Dr. Gulhan Unlu (University of Idaho).

Each of the five sections was assigned to one or more members of the committee for writing the initial draft. Through an exchange of drafts, several conference calls, and two meetings in Seattle, the final document was completed. This copy was then assembled into final shape, reviewed by a technical writer, and then reviewed by reviewers selected by Dr. Anjan Bose, who chairs the Report Review Committee of the WSAS but was otherwise uninvolved in the report. The document was then revised in light of the reviewers' comments. The reviewers were anonymous to the committee until the final acceptance and publication of the report. While not every member of the committee may agree with every statement, the report represents a consensus to which all members agreed.

The report should be interpreted in the context of the SOT. The committee recognizes scientific issues such as biodiversity and environment are associated with the development and use of GM plants and animals are not addressed in the SOT and, therefore, are not in the report. That these issues are not addressed in the report does not reflect their lesser importance to either the legislative sponsors or the committee but rather the specific focus of the SOT. The National Academy of Sciences has extensively addressed GM issues and is an authoritative source for evidence based information. In addition, there are clearly social values and perspectives regarding the use of GM organisms in agriculture and ingredients from GM plants and animals in foods. The committee recognizes the importance of these values and perspectives that will be reflected in the choice of an individual to support or oppose Initiative 522. Neither the committee nor the WSAS advocate or recommend for or against the passage of I-522. Finally, the SOT and the report do not address alternatives, such as voluntary labeling, or impacts if I-522 is defeated; the scope of the report is limited to the impacts if I-522 passes.

Many people besides the committee members contributed to the final document. Our special thanks go to Dr. Guy Palmer, Past President, WSAS, for his guidance and advice throughout this exercise, Dr. Robert Bates who oversaw the entire process, Sherri Willoughby for her many organizational contributions, and Laurel le Noble who was responsible for the final appearance of the document. We also express our gratitude to Dr. Anjan Bose (Washington State University) and the reviewers, Don A. Dillman (Washington State University); Jim K. Fredrickson (Pacific Northwest National Laboratory); Alan R. McCurdy (Washington State University); Edward L. Miles (University of Washington); Donald L. Patrick (University of Washington); Nancy F. Woods (University of Washington), who did an exemplary job under strict time constraints.

We hope this document will contribute to a better understanding of the many issues involved in the mandatory labeling of GM foods in Washington State.

Thomas Marsh, Co-Chair

Eugene Nester, Co-Chair

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Executive Summary

The committee addressed the **Statement of Task** using the best available science. In depth responses and references are provided in the body of the report. A brief summary is provided below for each of the 5 principal questions.

1. Definitions: *What products from genetically modified plants and animals are currently used to produce food ingredients? How do these plants and animals differ from non-genetically modified plants and animals?*

Genetically modified organisms, microbial, plant, and animal, are produced by using recombinant DNA technologies. In the 30 years since the first introduction and expression of a foreign gene into a plant, genetic engineering has revolutionized plant research and accelerated crop modifications, most notably, but not exclusively, herbicide resistance for weed control. More than 170 million hectares of genetically modified (GM) crops were grown worldwide in 2012. The three most common GM crops grown in the world are corn, soybean and cotton. In the United States, over 90% of these crops are now GM. Because of this, about 70% of the U.S. processed foods contain some ingredients from GM plants or products of GM plants. Potential new GM plant and animal entrants into the market that are of special importance to the Washington State economy are apples, potatoes, and salmon.

2. Nutrition: *How do the ingredients derived from genetically modified plants and animals that are incorporated into food differ from ingredients from non-genetically modified plants and animals? Do foods incorporating ingredients derived from genetically modified plants and animals differ in nutritional value as compared with foods incorporating ingredients from non-genetically modified plants and animals?*

The World Bank, the Organization for Economic Cooperation and Development (OECD), World Health Organization (WHO), United Nations Food and Agriculture Organization (UNFAO), and other international bodies have implemented standardized guidelines, procedures, and methods for analyzing and assessing nutritional qualities of food and food safety. Using these international standards, GM plants and animals are "substantially equivalent" to their non-GM counterparts. The chemical composition and nutritional value of GM products falls within the range of values found in non-GM products.

3. Food Safety: *Do foods incorporating ingredients derived from genetically modified plants and animals differ in safety, including infectious and non-infectious determinants, as compared with foods incorporating ingredients from non-genetically modified plants and animals?*

There have been no statistically significant, repeatable evidence of adverse human health consequences due to GM products. Given the current state of knowledge and evidence, GM foods are considered to "not differ" in safety as compared with foods with non-GM ingredients. Continued surveillance of food safety, including long-term health effects, is warranted for both GM and non-GM containing foods.

4. Policy and Trade: *How would a requirement for labeling be or not be congruent with existing labeling laws and trade regulations, both national and international? How likely is a labeling requirement to decrease or increase the price of food for consumers in Washington State? How likely is a labeling requirement to decrease or increase agricultural and processed food market opportunities and prices, within Washington State and for national and global exports? How likely is a labeling requirement to decrease or increase agricultural and processed food market opportunities and prices, within Washington State and for national and global exports?*

The lack of uniform standards, known as harmonization, and the potential for discrimination of policies among states and across countries and their agreements makes mandatory labeling of GM products a trade issue. Mandatory labeling, especially at a state versus federal level, is likely to affect trade and impose higher costs on firms producing and selling products in Washington. These costs are likely to be passed on to the consumer resulting in higher food prices. Importantly, these costs will be borne by firms and consumers for both GM and non-GM foods as labeling foods as non-GM will require oversight costs.

5. Regulation and Enforcement: *How would compliance be monitored and enforced? What are estimated costs associated with effective oversight and enforcement?*

Responsibility and costs for monitoring and compliance of I-522 would accrue to both the public and private firms; the estimates have a wide range, and could vary from a few hundred thousand to millions of dollars annually. The wide range reflects the lack of "after the fact" economic data and reliance on prospective estimates that have variable assumptions about the levels of administrative oversight, laboratory testing, and litigation associated with ensuring compliance.

Section 1: Definitions (Background)

Statement of Task: *What products from genetically modified plants and animals are currently used to produce food ingredients? How do these plants and animals differ from non-genetically modified plants and animals?*

I. Genetically Modified Organisms (GMOs)

GMOs are organisms modified by the application of recombinant DNA technologies. These techniques can involve the addition of specific genes from any organism into the plant/animal or the elimination or silencing of any gene(s) in the organism. At the present time, plants have been genetically modified primarily for herbicide resistance and/or insect resistance by introducing one or several genes from other organisms into the plants. These plants are called Transgenic. Genetic modification of plants is achieved primarily by using the plant pathogen *Agrobacterium* as a carrier/vector. This organism is a naturally occuring soil bacterium that transfers some of its genes into plants during infection. Because this gene transfer occurs in nature, *Agrobacterium* is frequently referred to as nature's genetic engineer.

II. Genetically Modified (GM) Plants and Animals

Products from Genetically Modified Plants and Animals Currently Used in Food

It has been three decades since the first successful introduction and expression of a desired foreign gene into a plant [1, 2]. During the last 30 years, genetic engineering has revolutionized plant research and accelerated crop improvements. The first GM food to reach U.S. consumers was the Flavr Savr® tomato, which received Food and Drug Administration approval in 1994. Papaya cultivation in Hawaii was threatened by Ringspot-Virus, a disease that dramatically lowers yield. In 1999, GM papaya plants resistant to the Ringspot-Virus were introduced, allowing farmers to cultivate this tropical fruit crop despite the virus being present in the environment. In recent years, genetic modification has expanded into almost every area of crop production. Because there is no legal requirement to inform consumers about the presence of GM products in food, it is very difficult to come up with a complete list of GM foods in the U.S. However, it is estimated that roughly 70% of processed foods in U.S. supermarkets contain GM ingredients or products from GM plants. That is primarily because many processed foods contain soybean and corn, and about 90% of these crops grown in the U.S. are GM.

In contrast to plants, GM animals have yet to reach the U.S. consumer. This is expected to change soon when genetically modified faster growing farmed salmon reach the market. These salmon are sterile and will be grown in tanks on land.

Percentage of Crops Grown World-Wide that are Genetically Modified

In recent years, the cultivation of GM crops has increased dramatically. It is estimated that in 2012, 170 million hectares of GM crops were grown in the world. The three most common GM

crops are corn, soybean, and cotton. Over 90% of the world's GM crops are grown in the U.S., Argentina, Brazil, Canada, China, and India. In contrast, most European countries do not allow the commercial production of GM crops.

Percentage of Crops Grown in the U.S. that are Genetically Modified

The five major GM crops in the U.S. are corn, soybean, cotton, canola, and sugar beet. Corn is the number one crop grown in the U.S., and nearly 90% is GM. In addition to being added to numerous processed foods, GM corn is a staple of animal feed. Over 90% of soybean is GM, and soybean oil is a staple of processed food. According to the U.S. Department of Agriculture, 94% of cotton is GM and vegetable oil, margarine, and shortening are derived from cottonseeds. About 90% of the U.S. canola crop is GM, and it is primarily used as cooking oil. About 90% of the sugar beet crop in the U.S. is also GM and is an important source of sugar. Another GM crop is the Hawaiian papaya. The transgenic papaya crop now covers about 1,000 hectares, which amounts to 75% of the total Hawaiian papaya crop. The other GM crops that are grown on a smaller scale in the U.S. are alfalfa and squash. The table below shows the major traits introduced into the commercially-grown GM plants in the U.S. Weeds compete with crops for water, nutrients, and light, thereby reducing the overall yield. Hence, crops that are tolerant to glyphosate, a popular herbicide (weed killer), have received the greatest attention.

Table 1-1. Examples of traits introduced into genetically modified plants that are now grown commercially in the United States

Introduced Trait	Crops
Tolerance to glyphosate herbicide	Corn, soybean, sugar beet, alfalfa
Resistance to pest attack	Cotton, corn
Resistance to certain viruses	Papaya, squash
Improved quality of oil and improved source of animal feed	Canola (rapeseed)

III. Differences Between GMOs and non-GMOs

The GMOs on the market today differ from non-GMOs in that GMOs contain a single or at most several genes from any source that are introduced into the plant/animal and confer the desired property on the organism such as resistance to herbicides or pests. These plants/animals products would be subject to mandatory labeling. Oils from GM plants contain no protein and therefore in themselves are not genetically modified. However, processed foods containing any oils from GM plants such as corn, soybeans, and canola would be subject to labeling. Genetic modification also occurs in non-GMOs after mutagenesis of seeds followed by conventional breeding and selection for the desired property. Such plants/animals products would not be subject to mandatory labeling.

IV. Likely New Plant and Animal Entrants in the Near Future

Many GM plant and animal products are in various stages of development that have not yet reached the consumer. However, J.R. Simplot Co. of Boise, Idaho has produced transgenic potatoes with a mix of genes from five potato varieties called Innate-brand potatoes (http://www.simplotplantsciences.com). These potatoes bruise less, do not brown when cut and decrease the potential for accumulation of carcinogens (which are produced when potatoes are cooked at high temperatures). The public comment period for these potatoes ended July 2, 2013, and they are likely to reach the market in about a year if the USDA accepts Simplot's request. Because Washington State has a major potato industry with an estimated economic impact of $4.6 billion (www.potatoes.com/our-industry/potatoes-and-economy) to the state, this development could have a major impact on the potato industry.

GM apples are not far behind. Okanagan Specialty Fruits, Inc. of Summerland B.C. has developed a transgenic apple called Arctic® Apple (http://www.arcticapples.com) that does not brown when sliced. One benefit is that pre-sliced, pre-packaged apples would not need preservatives, yet would retain their original color. The U.S. public comment period on a federal petition to approve these apples has passed, and they are expected to enter the market in the near future. The apple industry boosted the Washington economy by an estimated $7.02 billion in 2010-2011 (http://fruitgrowersnews.com/downloads/2012/WAC_Econ_ImpactReport_Final_082912.pdf). Because Washington State is world-renowned for its apples and currently no transgenic apples are being sold, any introduction of transgenic apples into the market is likely to have an impact on the fruit industry.

Transgenic fast-growing salmon were created in 1989 and have been under review by the FDA since 1995 (www.nature.com/news/transgenic-salmon-nears-approval-1.12903). The public comment period for this salmon ended April 26, 2013, and the salmon is likely to reach the market soon. Statewide salmon harvests, which contribute over $1 billion to the state's economy annually, according to estimates by the U.S. Department of Commerce, could be affected by this development (http://wdfw.wa.gov/hatcheries/overview.html).

Another major food crop that has been genetically modified and could soon enter the market is rice. Many transgenic rice plants with altered traits have been produced. One example is golden rice (http://www.goldenrice.com), that was genetically modified to be enriched with beta-carotene, the source of vitamin A which prevents blindness in children in the developing world. Genes from daffodil and bacteria were introduced into rice during the production of golden rice in 2000. Since then, new lines with higher levels of beta carotene have been developed using genes from bacteria and different plants such as corn. Even though this has received global attention, golden rice is still not commercially produced. However, because rice is not grown in Washington State, this development should not affect the state's agricultural sector.

V. Examples of Major Traits in Various Stages of Development for Introduction into Plants and Animals

Many GM plants and animals with a variety altered traits are being developed. In plants, these include: resistance to various herbicides, diseases and pests, improved stress tolerance, increased yields, improved nutritional quality and enhanced taste, improved shipping and storage qualities, and production of novel oils, plastics and pharmaceuticals.

In animals these include: increased yields of meat, fish, eggs and milk, increased nutritional quality of meat, milk, and other animal products, and improved animal health.

Section 2: Nutrition

Statement of Task: *How do the ingredients derived from genetically modified plants and animals that are incorporated into food differ from ingredients from non-genetically modified plants and animals?*

By definition, a GM plant or animal differs in at least one trait as compared with the non-GM parent. For regulatory purposes, the standard of "substantial equivalence" is used. This means that the concentrations of compounds and components within the GM plant or animal are within a range of values found in the non-GM variety [1, 2]. The guideline for substantial equivalence is recognized by regulatory agencies worldwide, including the World Health Organization (WHO), United Nations Food and Agricultural Organization (UNFAO), and the Organization for Economic Cooperation and Development (OECD) [2]. Thus, GM plants and animals are considered to be "substantially equivalent" to non-GMOs. However, a few exceptions do exist, and one example is "golden rice", engineered to produce higher levels of beta-carotene to combat vitamin A deficiency in children in certain parts of the world [4, 5, 6].

Do foods incorporating ingredients derived from genetically modified plants and animals differ in nutritional value as compared with foods incorporating ingredients from non-genetically modified plants and animals?

Nutritional assessments for foods from genetically engineered plants and animals that have been evaluated by the FDA through the consultation process have shown that such foods are as nutritious as foods from comparable non-GM varieties [1]. The nutritional values of these products from GM plants and animals are substantially equivalent and fall within the wide range of values.

The analytical methods used in food analysis are complex and undergo stringent scrutiny in the approval process [1]. This analysis must be reliable [3]. The GM plant or animal is substantially equivalent to its conventional counterparts by all of the analytical methods currently used [1].

Section 3: Food Safety

Statement of Task: *Do foods incorporating ingredients derived from genetically modified plants and animals differ in safety, including infectious and non-infectious determinants, as compared with foods incorporating ingredients from non-genetically modified plants and animals?*

GM products that are legally sold in the domestic U.S. markets have all gone through risk assessments conducted by appropriate regulatory agencies. In these risk assessments, the principle of substantial equivalence has been invoked to identify differences between the conventional food and GM food. One of the most common findings of these evaluations is that GM and non-GM sources produce similar nutritional performance and growth in animal models. GM foods have been effectively found "safe" given the current state of knowledge/evidence [1].

To date, no statistically significant, repeatable long-term adverse health effects from GM products on the domestic market have been documented in the scientific literature. Nevertheless, continued surveillance of long-term health effects from GM foods and food from conventional breeding is warranted [1]. Improving testing protocols and risk assessment approaches are prudent and consistent with this message. Some authors argue that most scientific investigations are short-term studies, mostly nutritional studies, with limited toxicological information [2, 3]. Therefore, long-term, thorough, and case-by-case scientific studies are recommended, for both GM plants and plants obtained by conventional breeding methods.

Section 4: Policy and Trade

Statement of Task: *How would a requirement for labeling be or not be congruent with existing labeling laws and trade regulations, both national and international? How likely is a labeling requirement to decrease or increase the price of food for consumers in Washington State? How likely is a labeling requirement to decrease or increase agricultural and processed food market opportunities and prices, within Washington State and for national and global exports?*

Existing GMO Labeling Laws and Regulations

Mandatory labeling laws exist in the European Union, Australia, New Zealand, Japan, and South Korea, with strict enforcement, while voluntary labeling of GMOs exists in Canada and the U.S. [1]. Other countries have mandatory labeling laws but without strict enforcement. In the U.S., GMO-labeling initiatives failed in Oregon, California, and New York. Connecticut and Maine recently passed GMO-labeling legislation contingent upon neighboring states passing GMO labeling laws. A number of other states have labeling laws that are currently under consideration (www.righttoknow-gmo.org).

Approval and regulation of GM crops in the U.S. is divided among the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and the United States Department of Agriculture - Animal and Plant Health Inspection Service (USDA-APHIS). FDA has the responsibility to ensure the safety of human food and animal feed, as well as proper labeling and safety of all plant-derived foods and feeds. In 2001, the FDA proposed voluntary guidelines for labeling food that does or does not contain GM ingredients. EPA regulates pesticides, including plants with plant-incorporated protectants such as Bt (*Bacillus thuringiensis*) toxin genes, to ensure public safety. This gene from the bacterium is responsible for the synthesis of a toxin. It also regulates pesticide residues on food and animal feed. APHIS regulates, through its Biotechnology Regulatory Services (BRS) program, the introduction of certain GMOs.

Trade

International trade guidelines fall under the purview of the World Trade Organization (WTO). In addition, individual countries or groups of countries have bilateral and regional (i.e., NAFTA) trade agreements that dictate trade terms and exchange opportunities. The lack of uniform standards known as harmonization and potential for discrimination of policies across countries and agreements make GMO labeling a domestic and international trade issue [2, 3, 4, 5, 6]. Economic concerns are that mandatory GMO labeling may create trade barriers or distort trade flows across states and countries.

Mandatory Labeling Impacts along the Supply Chain

Mandatory labeling could impose higher costs on firms. It would impose both additional direct costs (e.g., labeling of final product, segregation during production and transportation, certification/testing, and compliance costs) and additional indirect costs (managing GM and non-GM crops to mitigate cross-pollination and increased resistance in non-targeted insects and weeds) as the product moves down the supply chain to the consumer [3, 7]. The costs of actual labeling are a tiny fraction of the costs of compliance and certification [3]. The bulk of private costs arise in segregation of products along the supply chain [1, 3]. Moschini et al. [8] find that segregation of GMO and non-GMO products would increase costs to firms and increase food prices for consumers.

Other consequences to the supply chain from the growing of crops to the selling of the products in the stores have been debated. Some [1, 5] suggest that mandatory labeling could result in substitution by firms along the supply chain to higher-priced non-GM products and, consequently, stifle the adoption of GM technologies in Washington State; undermine competitiveness of Washington State food and products; and open the door for litigation against farms and firms along the supply chain for non-compliance. Others [9] contend there would be negligible relabeling and administrative costs, trivial increases in consumer prices, and minor litigation costs.

Mandatory Labeling Impacts for Consumers

Consumers make choices of goods to purchase contingent on the goods available, the relative price of the goods, their tastes and preferences, and their income levels. Labeling communicates to the consumer the quality attributes of a product [3, 6]. Some consumers may only want to know whether a product contains GMOs, and accept/reject the product based on that information. Other consumers may accept/reject the product based on GM content as well as competing products and price. Still other consumers may make their decision based only on price and non-GM attributes.

Several key outcomes are likely from I-522:

1) Consumers would be provided additional information about content of food products with which to make purchasing decisions.

2) Higher food prices would make consumers worse off, especially low-income consumers.

Proponents of mandatory GMO labeling appeal to the "right to know". Opponents point out that a menu of options currently exists for consumers from which to make a food choice. Currently consumers can choose between conventional unlabeled goods, organic foods, and voluntarily labeled GMO-free goods. By paying more, individuals desiring the "right to know" currently have the option to know when they are buying GMO-free goods, which are labeled voluntarily by firms targeting such individuals. Volunteer labeling concentrates the costs on the target group able and willing to pay more for GMO-free products. Caswell [6] points out that mandatory labeling imposes costs on everyone and not just those that desire GMO-free goods.

Balancing the "right to know" with the "right to choose" is an important economic tradeoff. Invoking GMO labeling through I-522 would provide additional information to consumers. However, I-522 could create barriers to production and marketing of GM products which could reduce the available number of goods to choose among (i.e., reduce the choices) and thereby restrict a consumer's "right to choose" [10]. In circumstances when the "right to know" conflicts with the "right to choose," laws and regulations must be carefully thought out, formed, and implemented.

Benefits and Costs of GMOs and Mandatory Labeling

The above discussion primarily identifies potential costs of mandatory labeling. Empirical studies quantify the benefits and costs to firms along the supply chain up to consumers [8, 11, 12, 13].

Benefits of GM crops from increased grower revenue through yields are documented [12, 13]. The GM insect resistant traits, used in corn and cotton, have accounted for more than 97% of the additional corn production and more than 99% of the additional cotton production [13]. Positive yield impacts from the use of this technology have occurred in all user countries when compared with average yields derived from crops using conventional technology. The average yield increase across the total area planted to these traits since 1996 has been more than 10% for corn and more than 15% for cotton. These data in part account for the use of GM seeds amongst growers.

In contrast to benefits accruing to GM crops, benefits to mandatory labeling are harder to assess and to quantify. For example, mandatory labeling for nutrition is beneficial because it is an aid for consumers in choosing a healthier diet [14]. Mandatory labeling for GMOs is less clear because there are no obvious nutritional differences between GMOs and non-GMOs. Research using stated preference approaches and experimental techniques report that consumers are willing to pay a positive but not large premium for GMO-free products. Using a meta-analysis, Lusk et al. [15] find that consumers on average placed anywhere from a 23% to 42% higher premium for non-GM food relative to GM food. To put this in perspective, premiums on organic foods relative to conventional foods are roughly double. Importantly, because no statistically significant, repeatable evidence of adverse human health consequences has been documented, GM products are not anticipated to decrease net benefits due to human morbidity or mortality. Finally, Alston & Sumner [5] report no positive benefits to mandatory GMO labeling. Zhao et al. [11] find voluntary labeling economically superior to mandatory labeling.

Section 5: Regulation and Enforcement

Statement of Task: *How would compliance be monitored and enforced? What are estimated costs associated with effective oversight and enforcement?*

I-522 would allow the Washington Department of Health to assess penalties against any individual or firm for violating the initiative. The fine would not exceed $1,000 per day [1]. Additionally, Washington State could collect revenues through fees. However, the number of penalties or fees is not available, and no state revenue can be estimated. Furthermore, possible county-level revenues and expenditures could result from civil actions filed in county courts.

Public costs on the food system

In addition to the private costs discussed in Section 4, additional public costs for monitoring and compliance will accrue to the government. From a theoretical standpoint, the framework of monitoring and enforcing compliance is straightforward. The State or a hired contractor will conduct audits at warehouses, processors, and/or retailers by taking samples of products and testing for the presence of GM ingredients. The State would then assess fines against those violating the regulation. However, measuring and quantifying the compliance, oversight, and enforcement costs will be difficult [2, 3].

Food-system compliance would begin with activities by supply-chain participants (i.e., testing, segregation, documentation, etc.; for a list of potential compliance activities by supply-chain participants, see Table 5-1). Reliable public and private cost estimates for mandatory GE labeling are not currently available [4]. However, several studies have estimated potential costs, which range from a negligible increase to as much as 10% of the total food cost [5, 6]. Potential compliance cost estimates for the supply-chain participants have been estimated for Oregon's Measure 27 in 2002 (see Table 5-2), California's Proposition 37, and Washington's Initiative 522 (see Table 5-3). In Measure 27, the estimated annual compliance costs ranged from $150 million to $920 million [7]. The California Legislative Analyst's Office estimated that an increase in administrative costs for reviewing documents and conducting audits could range from a few hundred thousand dollars to more than $1 million annually if Proposition 37 passed[8]. Additionally, there could be costs associated with litigation. According to the Washington State Office of Financial Management, the estimated compliance and enforcement costs for I-522 will be more than $0.2 million per year [1]. In a recent study [9], it was estimated that the Washington State government could spend up to $22.5 million annually to enforce I-522.

The Washington State government would incur additional costs for oversight and enforcement of I-522. In addition to a one-time startup cost, the government would incur annual costs for testing and conducting audits. According to Oregon's Department of Administrative Services, the estimated cost to Oregon's Department of Agriculture for enforcement of Measure 27 was $11.3 million per year plus a one-time startup cost of $6.5 million [7]. (For a break-out of these expenses, see Table 5-2.) In Washington, it is estimated that the program and rule development will cost

$1.24 million between 2014 and 2019 (see Table 5-3). Additionally, annual laboratory sampling and testing is estimated to cost $0.3 million per year (see Table 5-3). These estimates give a plausible range for the potential costs.

Table 5-1. Compliance Actions for Agricultural Products

Compliance Actions	Seed Producers	Farmers	Grain Elevators & Handlers	Processors & Manufacturers	Retail Stores & Food Services
Testing systems and supporting paper trails	✓	✓	✓	✓	✓
Product and production documentation	✓	✓			
Separate harvesting or cleaning systems	✓	✓	✓		
Separate storage, handling & transportation systems or cleaning systems	✓	✓	✓	✓	
Change contracting arrangements			✓	✓	
Separate processing lines or cleaning systems				✓	
Change inventory management systems			✓	✓	✓
Create and manage new SKUs				✓	✓
Create or modify labels	✓	✓	✓	✓	✓
Additional shelf space					✓
Operator training	✓	✓	✓	✓	✓
Liability insurance	✓	✓	✓	✓	✓

Source: Northbridge Environmental Management Consultants (2002)

Table 5-2. Oregon's Measure 27 Estimated State Expenditures

	Startup (One-Time)	Annual Costs	
		Million	New Positions Created
Testing Compliance at Food Service Environment	$2.80	$8.84	48
Testing Compliance at Retail Environment	$0.70	$2.26	13
Compliance Database	$3.00	$0.20	-
TOTAL	**$6.50**	**$11.30**	**61**

Cost Assumptions:

1) Collect and test 5,000 food samples/year in the retail environment for direct sales to consumer (including retail stores, distributors, and producers).

2) Audit 25,000 products/year in the retail environment at warehouses, processors, retailers, and ports.

3) Test 20,000 products/year in the food-service environment, including restaurants and other food-service providers (e.g., hospitals).

Table 5-3. Washington's Initiative 522 Estimated State Expenditures

Fiscal Year	2014	2015	2016	2017	2018	2019	Costs
Program Development	$82,000	$96,000	$210,000	$210,000	$210,000	$210,000	$1,018,000
Rule Development	$96,000	$122,000	$0	$0	$0	$0	$218,000
Compliance & Enforcement	$0	$0	$239,000	$231,000	$231,000	$231,000	$932,000
Laboratory Sampling & Testing	$0	$0	$300,000	$300,000	$300,000	$300,000	$1,200,000
TOTAL	**$178,000**	**$218,000**	**$749,000**	**$741,000**	**$741,000**	**$741,000**	**$3,368,000**

Source: Washington State Office of Financial Management (2013)

Cost Assumptions: There were no assumptions listed in the Fiscal Impact Statement.

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