GMO Legislative/Regulatory Risk
Updated Primer for May 2014

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Major Themes

State legislatures continue to consider Genetically Modified Organism (GMO) ingredient labeling legislation. Vermont in April became the third state to pass a mandatory labeling law. Meanwhile, an industry fronted proposal to require the FDA to establish voluntary nationwide GM labeling guidelines that would preempt state laws has generated little interest in Congress. For now, we believe GM labeling is likely to remain largely a state issue. We see the industry effort to establish a national standard as an acknowledgement they are unlikely to be able to continue to defeat mandatory labeling initiatives in the states.

State-based mandatory GM labeling carries several risks for the food, beverage and biotech industries, as we cover in-depth in earlier notes (http://www.capalphadc.com/wp-content/uploads/2014/01/gmo-01-10-14.pdf). We doubt state action on GMOs will cause a significant shift in the use and regulation of engineered crops or ingredients in the foreseeable future. However, the negative media attention the state debates generates could lead more food and beverage companies to explore "GM-Free" product lines, foster a larger market for non-GMO seeds and crops, and possibly create greater opportunities for "all natural" products.

Efforts to curb GMO use would affect bio-agriculture that produce genetically modified seeds (Monsanto, DuPont). It would widely apply to processed food and beverage manufacturers, where over 70% of their products contain GM ingredients (Kraft, Conagra, General Mills, Coke, Pepsi, Dr. Pepper, etc). Whole Foods and other manufacturers that market "all natural" products would benefit.

The following primer provides our updated analysis on GMO legislative and regulatory risk, as well as a range of resources from government and academic research on GMOs' impact on crop yield, commodity prices, and farm profits for your reference as the debate regarding GM labeling and use continues to unfold. We also provide background on how GM crops and ingredients are used in the US and how these products are regulated.

Please do not hesitate to let us know if you would like additional information or have suggestions for how this document could

GMO Federal and State Legislative Risk

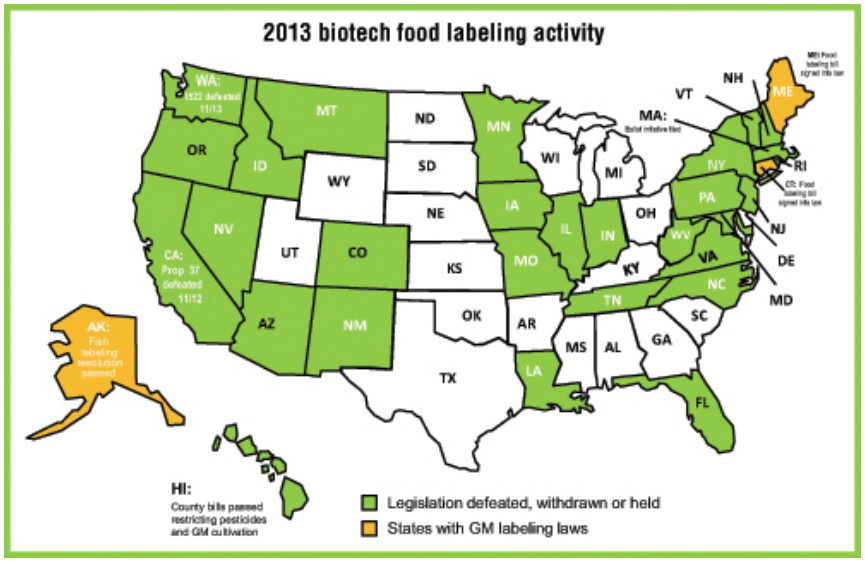
- GMO labeling bills are pending or are likely to be reintroduced in the 2014 session in 23 state legislatures.

- **New Vermont Law:** In April 2014, the Vermont legislature passed a mandatory labeling law that would go into effect starting in 2016. Importantly, it does not include the 5 state trigger. The Grocery Manufacturers Association is preparing to file a lawsuit to block the law. The Vermont legislature is among the most liberal in the country and was uniquely situated to pass its bill, as shown by the lack of a multi-state trigger that was necessary to pass the Maine and Connecticut laws - see below.

- **Existing Laws:** In 2013, Maine and Connecticut passed bills requiring food and beverages containing GM ingredients to be labeled as such, but 5 contiguous states with a total population of 20 million must pass similar measures for the laws to go into effect. An Alaska law pertains only to GM salmon.

- **Other State Developments:** In other state legislatures, the New Hampshire House recently voted down a GM labeling bill. Labeling legislation is likely to be approved by the New York State Assembly but is unlikely to clear the Senate. Massachusetts legislation is also a risk. A bill could proceed at the committee level this summer but is unlikely to pass this year. Overall, we doubt the five state trigger included in the Maine and Connecticut laws will be reached this year.

- **November Ballot Initiatives:** Labeling supporters are collecting signatures for mandatory labeling ballot initiatives in Oregon and Colorado that we expect to be offered in the November election after defeating an industry legal challenge to block the effort. A food and biotech industry coalition only narrowly defeated California and Washington GMO ballot initiatives, so the November ballots will be present risk going into the fall.



Source: The Miller Publishing Company

- **Federal Development:** Reps. Pompeo (R-KS) and Butterfield (D-NC) in April introduced industry-backed legislation (HR 4432) to require the FDA establish voluntary GMO labeling guidelines to head off a potential patchwork of mandatory state labeling laws. No Senate companion legislation has been introduced.

- **Odds:** We give 25% odds that Congress will act on GM legislation, and the Pompeo-Butterfield effort is likely to continue to face a difficult path. Mandatory GMO labeling bills have been introduced in Congress since the 1990's, and recent polling showing over 90% of Americans think food and beverage companies should be required to label GM-containing products are likely to continue to limit the prospects for the industry proposal.

- **FDA Reaction:** If states continue to pass labeling laws, it could prompt the FDA to issue voluntary labeling guidelines. However, guidelines do not have the strength of law or regulation and would not necessarily preempt the state mandatory labeling efforts.

- *Overall, we see industry's attempt to move a national, voluntary labeling standard as an indication it believes it cannot continue to win GM battles at the state level.*

GMO Regulation

Scope of GM Use in US Food Supply

- About 60-70% of processed food sold in the United States contains at least some GM material, primarily due to the prevalence of GM corn (75% of US acreage) and soybeans (~95% of US acreage). Nearly every major food and beverage company uses GM ingredients, and GM corn is often sold in grocery store produce sections. The non-profit consumer group Center for Food Safety has compiled a list of GM food products and manufacturers that is available here: http://www.centerforfoodsafety.org/files/shoppers-guide_final_24562.pdf

- GM varieties of flax, papaya, potatoes, radicchio, canola, rice, squash, sugar beets, tobacco, and tomatoes have also been approved for commercial use. GM sugar beets make up about 95% of the sugar beet market. However, the other products have either been withdrawn or are not widely planted in the US. The lack of market for these products typically stems from consumer resistance, as with GM tomatoes that were grown in the US in the 90's but have since disappeared.

- Monsanto sought approval for GM wheat in the mid-2000's that was approved by the FDA but withdrew its applications with the Environmental Protection Agency and USDA where approval is needed before bringing the product to market. Monsanto in 2009 stated it will take at least 10 years to develop a commercial variety of GM wheat. In addition to Monsanto, major GM seed manufacturers include DuPont, Dow, Syngenta, Bayer, Limagrain and Land O'Lakes.

- So far, there have been only very limited steps toward moving away from GM ingredients, such as General Mills offering a line of non-GMO Cheerios. Kashi offers several "Non-GMO" products and has pledged that over half of its offerings will be Non-GMO by 2015. Beverage companies almost exclusively use high fructose corn syrup derived from GM corn, so it may be difficult for them to develop Non-GMO products.

- On the retail side, Whole Foods has stated that its stores will label all GM products by 2018 and has a GMO-free policy for its in-store 365 brand. Interestingly, Whole Foods has also contributed heavily to the state GMO-labeling initiatives.

GM crops and products are regulated by three agencies, the Food and Drug Administration, the Environmental Protection Agency and the United States Department of Agriculture. In general, FDA's evaluates GM products' safety for consumption and has authority over food labeling; the EPA handles pesticide approvals, including "plant incorporated protectants" (PIP) produced by GM corn and cotton; and the USDA, through the Animal and Plant Inspection Service, assesses a GM product's potential impact on the environment, including non-GM crops.

FDA Overview

- FDA's authority over GM products is two-fold. First, it is responsible for ensuring that food and beverage products that reach the market are safe for human consumption. Second, the agency regulates products that employ recombinant DNA (rDNA, or the genetic piece that is added to an animal's or plant's DNA to alter its traits), which fit the definition of a drug under the Federal Food, Drug and Cosmetic Act.

- In 1992, FDA issued guidance stating that GMO's are "not inherently dangerous" and do not require special labeling or regulation. This guidance was codified in 1994 when FDA approved Celgene's GM tomato, ruling that it was "as safe as tomatoes bred by conventional means." Since then, the agency has not required other GM crops to undergo a rigorous scientific safety review simply because it is genetically engineered. Nor has it imposed any GM labeling requirements.

- However, the FDA does maintain other labeling policies pertaining to GMO's. *Products that contain GM ingredients cannot be labeled as "all natural."* The agency also issued draft voluntary guidance for producers who choose to label their products as "GMO-free." The Grocery Manufacturers Association has filed a petition with the FDA asking it to suspend the GM all natural restriction.

- In December 2012, FDA issued a preliminary evaluation of AquaSource's genetically modified salmon, the first application the agency has received for a GM animal, indicating it found no evidence the product posed a risk for human consumption or the environment. A final ruling on whether the GM salmon can be introduced into the marketplace is expected soon. Safeway and Kroger recently stated that they will not carry GM salmon if it is approved.

EPA and USDA Overview

- GM products that produce their own pesticides or plant-incorporated protectants (PIPs), such as GM corn, must receive approval from the EPA. Companies must comply with field tests and registration requirements, and the EPA must confirm that the level and type of pesticides a GM crop produces is safe for the environment and human consumption.

- The USDA has authority over new crops that are or may be "plant pests. A GM sponsor must receive approval from the USDA before its product is introduced into the environment, including field tests, or the marketplace.

- USDA approval is obtained through one of two processes: 1) the permit process, the most stringent regulatory path that requires significant testing; or 2) the notification process. Crops grown for pharmaceutical purposes are almost always require permit process approval, whereas crops intended for food are generally evaluated by the expedited notification process.

- Once a crop has been cleared by permit or notification testing, sponsors typically seek "non-regulation" status that allows them to market their product without further oversight or testing.

- GM crop non-regulation has generated significant controversy recently with several high profile court cases challenging USDA's environmental impact statements and analysis used for granting this status.

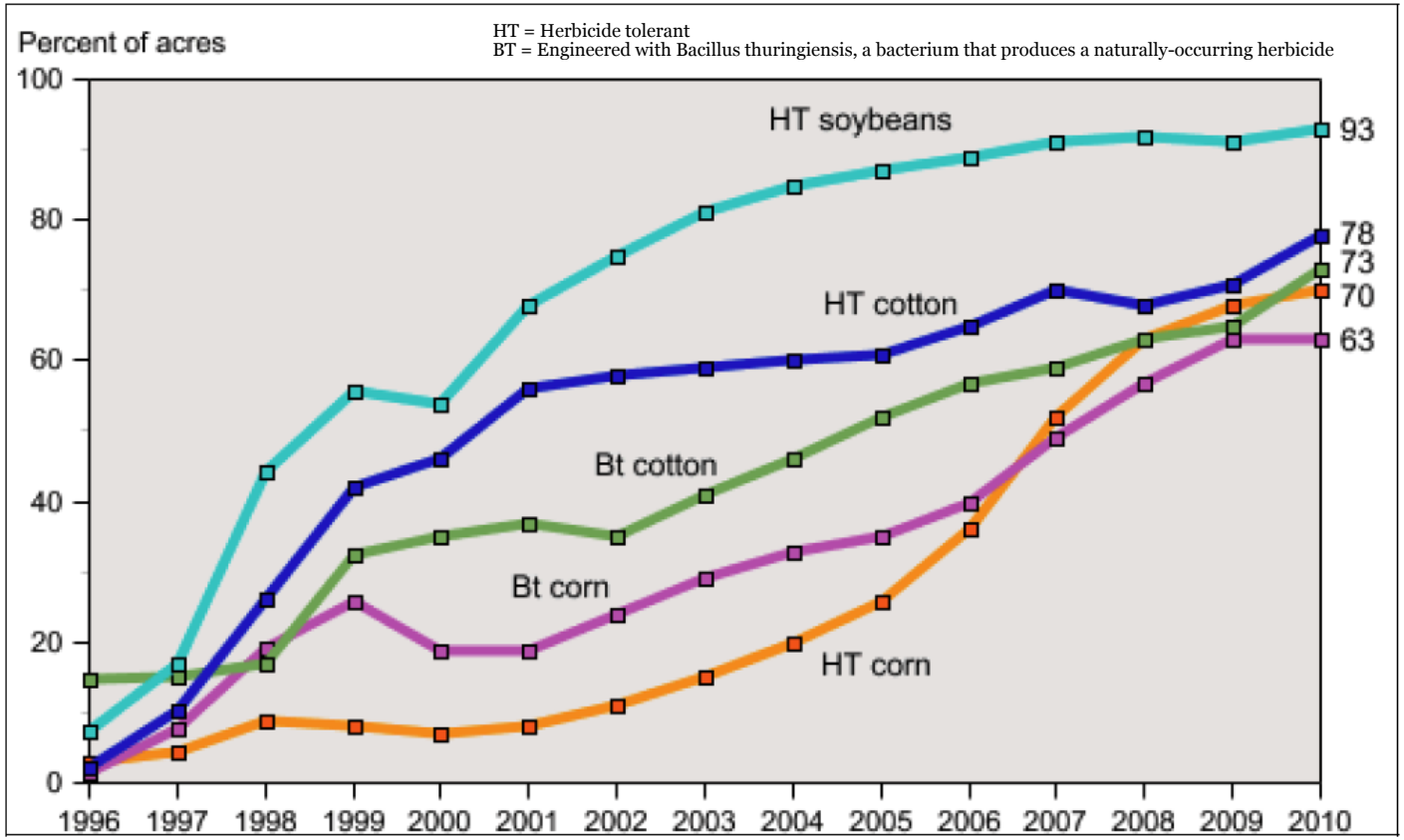
- In 2006, a federal court enjoined planting of GM deregulated alfalfa, which was overturned by the Supreme Court in 2010. In 2005, a USDA decision to deregulate sugar beets was overturned in federal court and the agency was required to redo its environmental impact analysis. The agency eventually moved to deregulate sugar beet root crops but not seed crops in 2011.

- For more background, please see the following Congressional Research Service report, *Agricultural Biotechnology: Background, Regulation and Policy Issues* (http://nationalaglawcenter.org/wp-content/uploads/assets/crs/RL32809.pdf)

GMO Adoption and Economic Impact

GM crop acreage has risen sharply since strains of soybeans, cotton and corn were introduced into the market in the 1990's. Today, herbicide tolerant (HT) soybeans make up 93% of total acreage, and HT and PIP corn and cotton make up the vast majority of those crops grown in the US.

Figure 1. Adoption of Genetically Engineered Crops in the United States, 1996-2010



Source: USDA Economic Research Service, "Adoption of Genetically Engineered Crops in the U.S."

Notes: Data for each crop also includes more recently developed varieties engineered with both herbicide tolerance and pest resistance traits. These multiple trait plants are referred to as "stacked trait" varieties.

- According to a comprehensive March 2013 analysis of the impact of GM adoption on farm profits in Landes Bioscience Journal, *The global income and production effects of genetically modified (GM) crops 1996–2011* (https://www.landesbioscience.com/journals/gmcrops/2013GMC0001R.pdf):

  At the global level, GM technology has had a significant positive impact on farm income, with in 2011, the direct global farm income benefit being $19.8 billion. This is equivalent to having added 6.2% to the value of global production of the four main crops of soybeans, maize, canola and cotton. Since 1996, farm incomes have increased by $98.2 billion.

- These comments track with a December 2012 USDA report, *Revisiting the Impact of Bt Corn on US Farm Profits*, which found (http://ageconsearch.umn.edu/bitstream/141671/2/fernandez-cornejo%20-%20current.pdf):

  On average, variable profits [in the US] were about $18 per acre higher for adopters [of GM corn] than for non-adopters, corn yields were 17 bushels per acre higher for adopters than for non-adopters, seed demand was 0.02 bushels per acre higher for adopters than for non-adopters, and insecticide demand was 0.04 pounds of active ingredients per acre lower for adopters than for non-adopters.

- We include charts detailing GM's impact on farm profits for insect resistant GM corn and herbicide tolerant GM soybeans, the two most common GM crops in the US, from the study's appendix on the next two pages. The full appendix can be found here - https://www.landesbioscience.com/journals/gmcrops/2012GMC0001R-Sup.pdf

GM IR corn (targeting corn boring pests) 2011

Country	Area of trait ('000 ha)	Yield assumption % change	Base yield (tonnes/ha)	Farm level price ($/tonne)	Cost of technology ($/ha)	Impact on costs, net of cost of technology ($/ha)	Change in farm income ($/ha)	Change in farm income at national level ('000 $)	Production impact ('000 tonnes)
US	22,330	+7	8.74	242	-22.5	-6.62	+141.83	+3,188,520	+14,638
Canada	841	+7	8.47	233	-20.8	-0.35	+137.88	+116,008	+499
Argentina	3,250	+5.5	5.55	166	-29.0	-29.0	+21.68	+70,467	+992
Philippines	557	+18	2.64	278	-39.0	-23.8	+108.5	+60,450	+265
South Africa	1,825	+10.6	2.48	221	-14.3	-2.0	+56.2	+102,514	+480
Spain	97	+12.6	10.38	287	-46.2	-37.7	+292.5	+28,570	+127
Uruguay	98	+5.5	4.06	291	-29.0	-29.0	+36.0	+3,527	+22
Honduras	30	+24	1.57	315	-30.0	-30.0	+88.9	+2,629	+11
Portugal	7	+12.5	5.75	272	-46.2	-46.2	+149.2	+1,152	+5
Czech Republic	8	+10	7.87	252	-46.2	-22.5	+175.9	+895	+4
Brazil	8,681	+20.1	3.85	230	-69.2	-46.2	+131.5	+1,141,400	+6,721
Colombia	52	+22	3.12	370	-48.4	+6.1	+259.9	+13,542	+36

Notes:

1. Impact on costs net of cost of technology = cost savings from reductions in pesticide costs, labour use, fuel use etc from which the additional cost (premium) of the technology has been deducted. For example (above) US cost savings from reduced expenditure on insecticides = +$15.88/ha, from which cost of technology which is shown as a negative 'in farm income terms' (-$22.5/ha) is deducted to leave a net impact on costs of -$6.62 (ie, a negative sign for impact on costs = an incease in costs so that the cost of the trait is greater than the savings on insecticide expenditure)
2. There are no Canadian-specific studies available, hence application of US study findings to the Canadian context (US being the nearest country for which relevant data is available)
3. 3. In the US, the adoption of pest protected (GM IR) seed has also allowed farmers to benefit from reduced crop damage insurance. This Biotechnology Endorsement Programme operated by the United States Department of Agriculture applied to about 4.9 million ha in 2011 and saved farmers a total of $168.4 million in insurance premia ($34.5/ha)

Source: The global income and production effects of genetically modified (GM) crops 1996–2011, GM Crops and Food: Biotechnology in Agriculture and the Food Chain 4:1, 74-83; January/February/March 2013; © 2013 Landes Bioscience

GM HT soybeans 2011 (excluding second crop soybeans – see separate table)

Country	Area of trait ('000 ha)	Yield assumption % change	Base yield (tonnes/ha)	Farm level price ($/tonne)	Cost of technology ($/ha)	Impact on costs, net of cost of technology ($/ha)	Change in farm income ($/ha)	Change in farm income at national level ('000 $)	Production impact ('000 tonnes)
US 1st generation	21,369	Nil	2.79	441	-32.64	+34.49	+34.49	+737,076	Nil
US 2nd generation	6,880	+10.4	2.72	441	-48.01	+19.12	+143.85	+989,660	+1,946
Canada 1st generation	666	Nil	2.75	446	-26.11	+18.55	+18.55	+12,354	Nil
Canada 2nd generation	444	+10.4	2.67	446	-44.49	+0.16	+124.12	+55,123	+123
Argentina	18,414	Nil	2.2	330	-2.5	+14.93	+14.93	+274,921	Nil
Brazil	20,531	Nil	2.65	513	-24.81	+20.76	+20.76	+426,239	Nil
Paraguay	2,619	Nil	1.5	400	-4.4	+13.03	+13.03	+34,126	Nil
South Africa	401	Nil	1.44	351	-24.67	+1.95	+1.95	+781	Nil
Uruguay	867	Nil	2.39	425	-2.5	+14.93	+14.93	+12,948	Nil
Mexico	15	+4	1.27	491	-23.56	-12.25	+12.71	+189	+0.8
Bolivia	966	+15	1.84	448	-3.32	+5.96	+106.68	+267	+267

Notes:

1. Price discount for GM soybeans relative to non GM soybeans in Bolivia of 2.7% - price for non GM soybeans was $460/tonne - price shown above is discounted

Source: The global income and production effects of genetically modified (GM) crops 1996–2011, GM Crops and Food: Biotechnology in Agriculture and the Food Chain 4:1, 74-83; January/February/March 2013; © 2013 Landes Bioscience

- A January 2010 study conducted by the Center for Agricultural and Rural Development at Iowa State University, *The Production and Price Impact of Biotech Crops*, provides a good overview of how global commodity prices would be affected if GM seeds were no longer used (http://www.card.iastate.edu/publications/DBS/PDFFiles/10wp503.pdf)

- As illustrated in the charts below, the researchers found that "world prices of corn, soybeans and canola would probably be, respectively, 5.8%, 9.6% and 3.8% higher, on average, than 2007 baseline levels if this technology was no longer available to farmers. Prices of key derivatives of soybeans (meal and oil) would also be between 5% and 9% higher, with rapeseed meal and oil prices being about 4% higher than baseline levels. World prices of related cereals and oilseeds would also be expected to be higher by 3% to 4%."

Figure 2: Increase in world commodity prices if biotech traits are no longer used

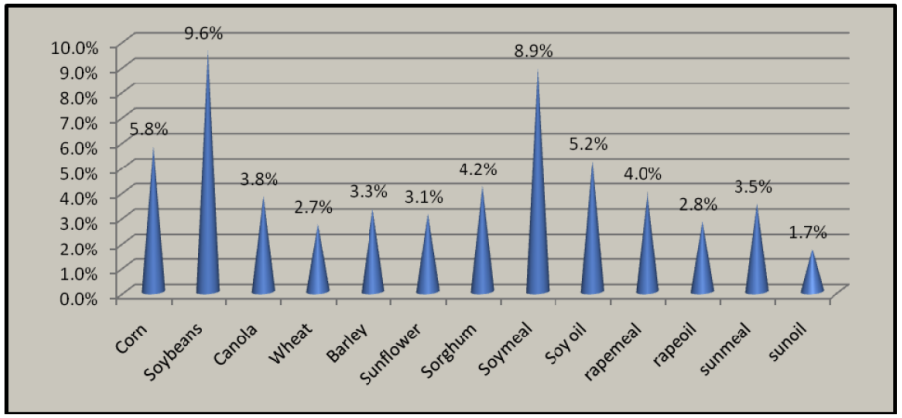
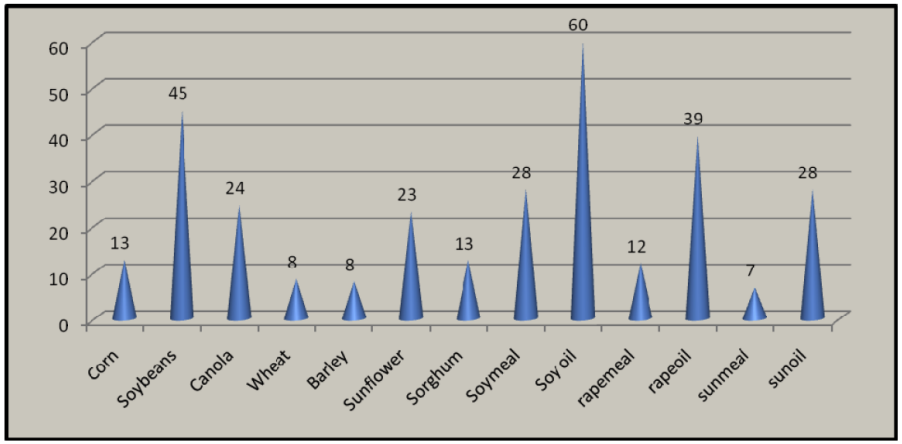


Figure 3: Increase in world commodity prices if biotech traits are no longer used ($/tonne)



Source: Iowa State University

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