

COMMITTEES:

APPROPRIATIONS  
BANKING  
INDIAN AFFAIRS  
VETERANS' AFFAIRS  
HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS

# United States Senate

SENATE HART BUILDING  
SUITE 706  
WASHINGTON, DC 20510  
202-224-2644

MONTANA TOLL FREE NUMBER  
1-866-554-4403

INTERNET:  
<http://tester.senate.gov/contact>

July 29, 2013

The Honorable Gene Dodaro  
Comptroller General  
Government Accountability Office  
123 GAO Place  
Washington, DC 20123

Dear Comptroller General Dodaro:

In 1984, the White House Office of Science and Technology Policy established the Coordinated Framework for Regulation of Biotechnology to balance health and safety regulation with regulatory flexibility to avoid impeding the growth of this industry. The laws and regulations that make up this framework have changed little since 1984. Accordingly, I ask you to review the Coordinated Framework, its relevant statutes and regulations, and its implementation by federal agencies to ensure that the regulation of genetically engineered crops fully reflects current science. In this study, GAO should address the below issues and questions:

## Food Safety

The effect of long-term consumption of genetically engineered food is generally assumed to be similar to that of consuming food bred through conventional means. However, the Food and Drug Administration's voluntary consultation process neither includes mandatory testing, nor provides an FDA endorsement of a food's safety. Rather, the process allows a company to make its own determination of safety. Even the limited consultation process is voluntary. The Food and Drug Administration proposed a rule in 2001 to require pre-market consultation on the basis that "there is greater potential for breeders...to develop and commercialize foods that are more likely to present legal status issues and thus require greater FDA scrutiny than those developed using traditional or other breeding techniques." This rule was never finalized.

- **Given FDA's recognition of the heightened issues arising under food safety laws when food is genetically modified, does the current voluntary consultation process provide sufficient protection from human health issues arising from long-term consumption of genetically engineered foods? Does the current process ensure that sufficient data to ensure safety is developed before genetically engineered crops are marketed to consumers?**

## International Trade

Some major export markets for American agricultural products do not allow any genetically modified crops, and the presence of genetically modified varieties in the U.S. market has led some export markets to restrict trade of entire classes of commodities.

- **Does the coordinated framework give regulatory agencies the ability to factor the economic impact of the loss of sensitive international markets into deregulation decisions? How have regulatory agencies provided for losses arising from foreign barriers to U.S. commodities stemming from the presence of genetically modified organisms in commerce?**

### **Oversight of Experimental Crops**

The recent unapproved release of a variety of genetically modified wheat is only the latest in a series of economically damaging unapproved releases of regulated crops. These releases undermine consumer confidence and international markets, and call into question the effectiveness of oversight of field testing. A similar release of a crop engineered to produce pharmaceuticals or industrial chemicals could pose serious threats to human health.

- **How can agency oversight of field trials of new genetically engineered plants be improved to prevent unapproved releases? How have agencies considered the potential economic and health consequences of release when approving field testing, and how can this approval process be improved?**

### **Non-Food Industrial Crops**

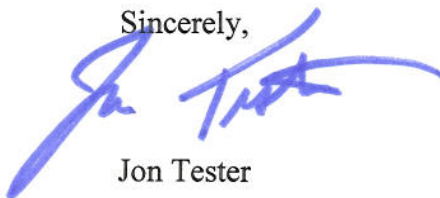
Modern biotechnology has allowed crops to be developed with traits that enhance their performance for certain uses at the expense of their suitability for others. Examples include traditional food grains enhanced for ethanol production, but made nearly useless for food processing. Traditional food crops may also be engineered to produce commercial pharmaceuticals or chemicals, though the presence of these products in crops intended for food or feed could render them worthless if discovered, and potentially harmful if undetected. As functional crops developed for specific end uses become more commonplace, it will be increasingly important to manage unintended cross-pollination and contamination during harvest, processing and storage.

- **How effectively does the coordinated framework allow for the management of cross-pollination between crops genetically engineered to have incompatible end uses with other varieties of the same crop? How have regulatory agencies provided for on-farm economic losses that will arise from food crop contamination by varieties with incompatible traits, such as chemical or fuel production, through cross-pollination, commingling, or other pathways? Does the coordinated framework permit regulatory agencies to factor economic and health risks of unintended gene flow into deregulation decisions?**

Finally, please review whether the coordinated framework has adequately evolved in accord with the experiences of the industry and the agencies, and what administrative or legislative changes may be needed to effectively protect human health and the environment as the next generation of genetically modified crops reach commercialization.

Thank you very much for your attention to this request.

Sincerely,



Jon Tester