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CONTENTS

Climate Change Challenges, GE Crop Controversies, and a "GE Food" Label Law

Phill Jones

In their June 20, 2016, Nature Climate Change article, University of Leeds researchers sounded a warning about a threat to agriculture. Lead author Andy Challinor and his colleagues explain that breeding and cultivating a new crop variety can require up to 30 years of effort. Considering the rate of temperature increase in the tropics, a new crop that is finally ready for cultivation by farmers will be grown in temperatures that are warmer than the temperatures in which the crop was developed.

"In Africa," said Challinor in a press release, "gradually rising temperatures and more droughts and heatwaves caused by climate change will have an impact on maize." Higher temperatures cause a shorter crop duration – the length of time between planting and harvesting – and this results in less time for plants to accumulate biomass, which means smaller yields. By 2031, most of Africa's maize-growing regions will experience shorter crop durations, causing shortages in a staple food.

Challinor suggests that the amount of time needed to breed a new crop variety may be reduced by using marker aided-selection to identify certain traits. Teams in Ethiopia, Kenya, and Zimbabwe are taking a different approach: Breeding new varieties in warmer temperatures to select for increased heat tolerance. "Mitigating future climate change to within the agreed 'safe limit' will also ensure that new crop varieties can survive," Challinor said in an article posted on the *AllAfrica* website. "This will become particularly important in the second half of this century, when changes we make now in reducing emissions will begin to show their effects."

USDA Embitters Farmers of GE Sugarbeets

During May, the USDA announced that it would allow an additional 200,000 tons of raw cane sugar into the United States, a move to supplement sugar from genetically engineered (GE) sugarbeets. This would maintain an adequate sugar supply, the USDA said, despite a market plagued with uncertainty due to the lack of GE labeling legislation.

Duane Grant told Chris Clayton of *DTN/The Progressive Farmer* that the potential for market uncertainty is exaggerated. Grant is a sugarbeet grower and chairman of the board for sugarbeet processor Amalgamated Sugar. He said that sugarbeet growers are running at capacity and selling sugar at prices on par with sugar cane.

As a grower of 7,000 acres of sugarbeets, Grant finds that the GE food labeling debates overlook the fact that GE sugarbeets are cultivated in a more environmentally-friendly way, compared with conventional sugarbeets. "The change was just dramatic," he told Clayton. "We were able to park our plow and go to no-till farming techniques.

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We were able to close the door on the insecticide and herbicide shed and stop using a mixture of six or seven different herbicides."

GE food labeling debates also obscure the fact that scientific analyses fail to distinguish sugar refined from GE sugarbeets, conventional sugarbeets, and sugar cane. Sucrose is sucrose.

Luther Markwart, executive vice president of the American Sugarbeet Association, told Clayton that "American agriculture has not educated American consumers the way they should have. It was always someone else's job to do and then you have got activists, frankly, out there scaring people." Markwart's view echoes that of the USDA, which stated that uncertainty in the sugar market is due in part to a "lack of consumer information about genetic technology."

Consumers Come Up Short in Their Knowledge About GE Crops

Brandon R. McFadden, assistant professor in the Department of Food and Resource Economics at the University of Florida and Jayson Lusk, an agricultural economics professor at Oklahoma State University, wondered about the information that supported consumers' beliefs about GE food and a demand for mandatory labeling. They performed an online survey that was completed by 1,004 participants. "Results suggest consumers think they know more than they actually do about GM food," McFadden and Lusk wrote in their report.

Many respondents claimed to oppose GE food even though they had a clear lack of knowledge about the subject. For example, 84% supported mandatory labeling for food containing GE ingredients, which was about the same number of respondents who supported a label for food indicating the presence or absence of DNA.

"Our research indicates," McFadden said in a press release, "that the term 'GM' may imply to consumers that genetic modification alters the genetic structure of an organism, while other breeding techniques do not." Other evidence for the notion that consumers may have very little knowledge about genetics include the 33% who thought that conventional tomatoes lacked genes, and the 32% who thought that vegetables do not have DNA.

Does support for DNA labeling indicate ignorance about genetics or does it reflect the psychology behind the ways that consumers handle difficult questions? "It has been argued," McFadden and Lusk wrote, "that individuals attempt to economize on scarce cognitive resources by unconsciously substituting an easier question for a hard one. Rather than seriously weighing the pros and cons of a mandatory labeling, the similarity in responses to the DNA labeling question suggests people may instead be substituting these questions with a simpler question like, 'do you want free information about a topic for which you know very little?'"

A "Bioengineered Food" Labeling Law

On July 1, 2016, Vermont became the first state to require that food produced by genetic engineering must be labeled as such. Although the law has been

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ISB welcomes your comments and encourages article submissions. If you have a suitable article relevant to our coverage of agricultural and environmental applications of genetic engineering, please email it to the Editor for consideration.

in effect since July 1, the state government did not plan to enforce the law until 2017. This strategy is just as well; the federal government nullified Vermont's labeling effort.

In June, US Senator Pat Roberts (R-KS), chairman of the US Senate Committee on Agriculture, Nutrition, and Forestry, and ranking member Debbie Stabenow (D-MI) introduced a bipartisan proposal to provide consumers with information about food produced by genetic engineering. "Unless we act now," Roberts said, "Vermont law denigrating biotechnology and causing confusion in the marketplace is the law of the land. Our marketplace – both consumers and producers – needs a national biotechnology standard to avoid chaos in interstate commerce."

To prevent states from weaving a patchwork of labeling regulations, the proposed legislation included a federal preemption clause that prohibits states, or a political subdivision of a state, from mandating the labeling of food or seed that is genetically engineered. The legislation provides manufacturers with several labeling options, such as text on the label, a symbol, or an electronically scannable label that would offer information about the food. Small manufacturers can satisfy the disclosure requirement by providing telephone numbers or website addresses, whereas very small manufacturers and restaurant owners would be exempt from the disclosure requirements. The legislation requires the US Department of Agriculture to establish through rulemaking a national uniform standard for the labeling of bioengineered food produced for humans. The USDA's Agricultural Marketing Service has two years to finalize these rules.

The legislation includes a number of exemptions, such as foods containing meat, poultry, or eggs as the main ingredient. The fact that livestock had consumed feed made from GE crops does not trigger the labeling requirement. The US Food and Drug Administration took the position that the legislation's definition of food that must be labeled would exclude many ingredients produced from GE plants, such as sugar, starch, and soy oil.

The Senate and the House of Representatives passed the labeling bill in July. Critics of the legislation urged President Obama to veto the legislation, arguing that electronically scannable labels would deny information to consumers who do not have smartphones. They also voiced concern that the bill exempts food produced from RNA interference, CRISPR, and other newer technologies. This claim is based upon the legislation's definition of bioengineered food as food "(A) that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature."

On July 29, 2016, President Obama signed the legislation into law. A section entitled "National bioengineered food disclosure standard" is tucked within S.764, "A Bill to Reauthorize and Amend the National Sea Grant College Program Act, and for other Purposes."

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Food and Drug Administration, HHS

Notice of availability of a draft guidance for industry (GFI) #187 entitled "Regulation of Intentionally Altered Genomic DNA in Animals."

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #187 entitled "Regulation of Intentionally Altered Genomic DNA in Animals." This draft guidance revises GFI #187 entitled "Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs" (current GFI #187). Current GFI #187 clarifies FDA's requirements and recommendations for producers and developers of genetically engineered (GE) animals and their products. It describes how the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) apply with respect to GE animals. This draft revision of current GFI #187 expands the scope of the guidance to include animals intentionally altered through use of genome editing techniques. The draft revised GFI #187 now applies to "those animals whose genomes have been intentionally altered using modern molecular technologies." The Agency is seeking comment on the draft revised GFI #187, including the nomenclature that best describes these animals and on any existing empirical evidence indicating that certain types of genome editing may pose minimal risk.

DATES:

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written

comments on the draft guidance by April 19, 2017.

ADDRESSES:

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2008-D-0394 for "Regulation of Intentionally Altered Genomic DNA in Animals." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box

and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Laura R. Epstein, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-796-8558, laura.epstein@fda.hhs.gov.

Source:

Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Availability. Federal Register. https://www.federalregister.gov/documents/2017/01/19/2017-00839/regulation-of-intentionally-altered-genomic-dna-in-animals-draft-guidance-for-industry-availability

Pesticide Use Related to GE Crops and Farmer Health in China: Evidence and Implications

Chao Zhang and Ruifa Hu

Introduction

Although glyphosate, an herbicide commonly used on genetically engineered (GE) herbicide tolerant crops, is considered to be one of the least toxic pesticides[1-2], there is still a growing public concern about the safety of glyphosate and even GE crops[3-5]. In March 2015, a publication in the journal Lancet Oncology disclosed that the evaluations from the International Agency for Research on Cancer (IARC) classified glyphosate as a probable carcinogenic substance to humans, which led to an intensive debate[6-9]. The report from IARC was questioned for their lack of dose-effect analysis and failure to include all the available studies in the evaluations[8-10]. As noted, the adoption of GE glyphosate-tolerant crops increases glyphosate use but reduces non-glyphosate herbicide use; and adoption of GE insect-resistant crops significantly reduces insecticide use and changes the types of insecticides[11-17] used.

It is important to evaluate the effects of different pesticides used with GE crops on farmer health. The scientific literature focusing on this issue in an integrated framework is scant. Our study estimated the dose effect of agricultural uses of different pesticides used with GE crops on farmer health.

Research Approach

In 2012, a sample of 224 farmers in three Chinese provinces (Guangdong, Jiangxi and Hebei) were randomly selected to take part in two rounds of health checks. The first round was performed in March before crop planting in three provinces, while the second round was performed in August in Jiangxi and Hebei, and in December in Guangdong, prior to the end of crop harvest. Blood samples were evaluated for 35 health indicators using a blood chemistry panel and peripheral nerve conduction test.

All pesticides used by the sampled farmers were recorded and then classified into six groups: glyphosate, non-glyphosate herbicides, chemical lepidopteran insecticides, biological lepidopteran insecticides, non-lepidopteran insecticides, and fungicides. The first three types are used with GE crops.

To determine the dose effect of pesticide use on farmer health and control the confounding effect of other factors on the health indicators, the multivariate linear regression analyses were developed as follows:

$$HI_i = \alpha + \beta \cdot Pesticide_i + \gamma \cdot Characteristics_i + \delta \cdot Habit_i + \lambda \cdot Region_i + \zeta \cdot BaseHI_i + e_i,$$

where 'HI' is the indicator of the second round of health checks; 'Pesticide' is a group of variables of pesticide use, including glyphosate, non-glyphosate herbicides, chemical lepidopteran insecticides, biological lepidopteran insecticides, non-lepidopteran insecticides and fungicides; 'Characteristics' describes farmers' demographic characteristics, including age, gender and body mass index; 'Habit' is a group of dummy variables of cigarette intake, alcohol consumption. and protective measure' 'Region' includes two provincial dummies of Guangdong and Jiangxi; and 'BaseHI' is the indicator of the first round of health checks (measuring the baseline health status) corresponding to that of the second round.

Results

Table 1 shows that, on average, each farmer used a total of 4.54 kg of pesticides in 2012. Agricultural herbicide use was only second to insecticide use, and glyphosate (0.60 kg) accounted for about half of the total use of herbicides. Agricultural use of lepidopteran insecticides dominated insecticide use, and the majority of lepidopteran insecticides were chemicals, of which the amount averaged 2.10 kg. The average amount of non-lepidopteran insecticides was 0.27 kg, much lower than that of lepidopteran ones. Compared with herbicides and insecticides, the amount of fungicides used by farmers was only 0.68 kg on average, accounting for only 15% of the total use of pesticides.

Table 1. Agricultural pesticide use of the sample farmers

Variable	Unit	Mean ± Standard Deviation
Total pesticide use	kg	4.54 ± 5.52
Glyphosate	kg	0.60 ± 1.57
Non-glyphosate herbicides	kg	0.61 ± 1.77
Lepidopteran insecticides	kg	2.38 ± 3.44
Chemical insecticides	kg	2.10 ± 3.41
Biological insecticides	kg	0.28 ± 0.83
Non-lepidopteran insecticides	kg	0.27 ± 0.69
Fungicides	kg	0.68 ± 1.56

The estimated coefficients of agricultural pesticide use are summarized in **Table 2**. The results show that glyphosate use was not significantly associated with any indicator in the blood chemistry panel or with peripheral nerve conduction; therefore, it could be concluded that glyphosate use is not likely to induce negative effect on health. In contrast, the use of non-glyphosate herbicides was positively associated with blood urea nitrogen (BUN) and creatinine (Cr), two indicators of renal function, and negatively associated with serum folic acid (VB_9). The results demonstrate that non-glyphosate herbicides inclined to increase the risks of renal dysfunction and decrease serum folic acid. We failed to observe a significant association between non-glyphosate herbicides use and any nerve indicator, including peripheral nerve conduction.

We observed contrasting results for the different types of insecticide used. Chemical lepidopteran insecticides were significantly associated with increases in alanine aminotransferase (ALT), serum glucose (GLU), and C-reactive protein (CRP). These results demonstrate that substantial use of chemical lepidopteran insecticides is likely to damage hepatic function, increase the serum glucose, and induce the inflammation among farmers. We also observed that agricultural use of chemical lepidopteran insecticides was negatively associated with the motor conduction velocities of the median (MMCV), ulnar (UMCV), tibial (TMCV) and common peroneal (PMCV) nerves, and the sensory conduction velocities of the median (MSCV) and ulnar (USCV) nerves. In addition, there was a significantly positive association between chemical lepidopteran insecticides use and the distal motor latency of the ulnar nerve (UDML).

Based on these results, we conclude that the potential of chemical lepidopteran insecticides to damage peripheral nerves, especially the median and ulnar nerves, is severe. However, there is not a significant association between either biological lepidopteran or non-lepidopteran insecticides use and the blood chemistry panel or peripheral nerve conduction; therefore, biological insecticides against lepidopterans do not appear to affect farmer health indices. Likewise, the insecticides used to control non-lepidopteran insects did not induce adverse effects on farmer health, which could be attributed to the relative small amount of these insecticides used, which was not enough to induce health risks.

The results also show that the adverse health effect of fungicide use was obvious. We found that fungicide use was significantly associated with ALT and aspartate aminotransferase (AST), two crucial indicators of hepatic function, as well as negatively associated with vitamin B_{12} (VB_{12}), which demonstrates that fungicide use was likely to damage hepatic function and induce the loss of vitamin B_{12} among farmers. As to peripheral nerve conduction, fungicide use was not associated with any indicator of the motor nerve conduction, but there was a significantly negative association between fungicide use and the sensory nerve action potential amplitude of ulnar nerve (USNAP).

Table 2. Estimated coefficients of agricultural uses of pesticides related to GE crops on farmer health

Indicator	Glyphosate	Non-glyphosate herbicides	Chemical lepidopteran insecticides	Biological lepidopteran insecticides	Non-lepidopteran insecticides	Fungicides
Blood chemistry panel						
ALT (U/L)	–0.58	–0.05	0.65**	–0.17	–0.55	1.43*
AST (U/L)	–0.06	0.31	0.30	–0.20	0.04	1.64**
BUN (mmol/L)	–0.05	0.10*	0.02	–0.12	–0.23	0.11
Cr (μmol/L)	–0.53	1.75**	–0.21	–0.29	–1.27	0.28
VB_{12} (ng/L)	–0.82	–1.55	–1.02	–6.97	24.10	–19.81*
VB_9 (μg/L)	–0.17	–0.35*	–0.00	0.30	–0.25	0.10
GLU (mmol/L)	0.03	0.01	0.04*	0.05	–0.13	–0.01
CRP (mg/L)	–0.24	–0.05	0.25*	0.16	–0.67	0.07
Peripheral nerve conduction						
MMCV (m/s)	0.18	–0.05	–0.20*	–0.13	0.02	0.28
UMCV (m/s)	0.23	–0.14	–0.20*	–0.16	0.25	–0.18
TMCV (m/s)	–0.32	–0.11	–0.19*	–0.06	–0.12	–0.05
PMCV (m/s)	0.00	–0.04	–0.18**	0.38	–0.34	–0.18
MSCV (m/s)	0.00	–0.34	–0.19*	0.22	0.50	0.08
USCV (m/s)	0.16	–0.04	–0.20*	–0.28	–0.45	–0.16
UDML (ms)	–0.01	–0.00	0.01*	–0.05	0.02	0.01
USNAP (mV)	–0.06	0.11	0.04	0.06	0.06	–0.20**

Note: ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; Cr: creatinine; VB_{12}: vitamin B_{12}; VB_9: serum folic acid; GLU: serum glucose; CRP: C-reactive protein; MMCV: motor conduction velocity of the median nerve; UMCV: motor conduction velocity of the ulnar nerve; TMCV: motor conduction velocity of the tibial nerve; PMCV: motor conduction velocity of the common peroneal nerve; UDML: distal motor latency of the ulnar nerve; MSCV: sensory conduction velocity of the median nerve; USCV: sensory conduction velocity of the ulnar nerve; USNAP: sensory nerve action potential amplitude of the ulnar nerve. ** $p < 0.01$, and * $p < 0.05$.

Conclusions

Our results demonstrate that the adverse health effects of insecticide use was more severe than that of herbicides and fungicides. Glyphosate use was not associated with farmer health damage, while the use of non-glyphosate herbicides inclined to induce renal dysfunction and decrease of serum folic acid. Moreover, chemical lepidopteran insecticides were likely to damage hepatic function, increase serum glucose level, and induce the inflammation, as well as induce damage to peripheral nerves among farmers.

As mentioned above, agricultural uses of glyphosate, non-glyphosate herbicides, and lepidopteran insecticides may be significantly altered as GE glyphosate-tolerant and insect-resistant crops are adopted. This implies that the adoption of GE glyphosate-tolerant crops may benefit farmer health by sharply reducing the use of the more toxic non-glyphosate herbicides, although glyphosate use may correspondingly increase to a certain extent.

In addition, since GE insect-resistant crops may substantially reduce the use of chemical lepidopteran insecticides, the alterations in insecticide use due to the adoption of GE insect-resistant crops may also benefit farmer health by lowering the insecticide exposure levels if GE insect-resistant crops are adopted. Hence, this study could have positive implications for the development of GE crops.

Source: Zhang, C., Hu, R., Huang, J., Huang, X., Shi, G., Li, Y., Yin, Y., and Chen, Z. (2016). Health Effect of Agricultural Pesticide Use in China: Implications for the Development of GM Crops. Scientific Reports. doi:10.1038/srep34918

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