April 20, 2011

This cover letter is provided to explain the reasoning and concerns that were conveyed in a private letter that I sent to Secretary of Agriculture, Thomas Vilsack on January 17, 2011 (Attachment 1). The letter was not intended for public disclosure; however, the letter was 'leaked' and subsequently posted on the internet from which it soon became public knowledge world-wide. My busy meeting, research, and travel schedule has delayed getting further information on this matter out publicly to the many individuals who have requested it. There is much research still needed in order to understand the interactions of this new "organism" in crop and animal production, and offers to participate in the investigation are welcomed. The scientific data on this newly recognized organism is being prepared for formal publication.

I wrote the letter to Secretary Vilsack for a very simple reason: we are experiencing a large number of problems in production agriculture in the U.S. that appear to be intensified and sometimes directly related to genetically engineered (GMO) crops, and/or the products they were engineered to tolerate – especially those related to glyphosate (the active chemical in Roundup® herbicide and generic versions of this herbicide). We have witnessed a deterioration in the plant health of corn, soybean, wheat and other crops recently with unexplained epidemics of sudden death syndrome of soybean (SDS), Goss' wilt of corn, and take-all of small grain crops the last two years. At the same time, there has been an increasing frequency of previously unexplained animal (cattle, pig, horse, poultry) infertility and spontaneous abortions. These situations are threatening the economic viability of both crop and animal producers.

There were four specific purposes of my private letter to Secretary Vilsack:

- 1) to bring to his attention the possible association of the increasing severity of both plant and animal diseases that are severely impacting our production efficiency with the expanding use of the herbicide glyphosate;
- 2) to request greater caution and to delay deregulating additional Roundup Ready® (RR) crops (alfalfa and sugar beets) until the possible causal/predisposing relationships with glyphosate and/or RR plants can be ruled out as a threat to crop and animal production;
- 3) to alert him to the presence of the new electron microscopic organism that appears to be widespread, increasing in frequency, and impacting the health and productivity of *both* plants and animals (which is very rare); and
- 4) to ask for the critical funding and scientific expertise necessary to understand the plant and animal epidemiological and etiological relationships with this new electron microscopic organism that are necessary to insure production efficiency and feed/food safety.

Summary of Findings

The following information has been developed by Agronomists, Plant Pathologists, Plant Physiologists, Microbiologists, Molecular Biologists and Veterinary Scientists.

Identification of a New Organism in Crops and Feed

Currently, there is an increase in fetal losses with an unknown etiology in animals. Incidence of high infertility and spontaneous abortions in the various animal species is becoming more common. Often, all previously known causes of these conditions can be ruled out as factors for these particular farm operations (Attachment 2). A suspect agent has been isolated from these

fetal losses, where no other cause can be found. Detailed examination for the newly recognized organism has shown its presence in all of the cases examined to date. Koch's postulates have been completed for animals to verify the cause/effect relationship with this newly culturable organism. A search for the source of animal infections revealed a high population of this newly discovered electron microscopic sized organism in high concentrations in the soybean meal component of animal feed. It also has been observed in soil, fungal mycelia, soybean leaves and meal, various corn tissues, distillers meal, and fermentation feed products (corn silage, haylage, wheatlage, etc.). The new organism is in very low concentrations or absent from the non-GMO plants and grain samples evaluated to date.

The organism occurs in especially high concentrations in leaves and other tissues of soybean plants expressing severe sudden death syndrome (SDS) caused by the soilborne fungus *Fusarium solani* fsp *glycines*, and corn with severe Goss' wilt caused by the gram+ bacterium *Clavibacter michiganense* subsp. *nebraskensis* infections. It also has been found present in mycelia of the *Fusarium* spp. causing SDS. SDS and Goss' wilt are just two of the many plant diseases that are increased by glyphosate, as is root infection by *Fusarium* spp. (Fernandez et al, 2009; Johal and Huber, 2009; Kremer and Means, 2009; Yamada et al, 2009). Although *Fusarium* culture filtrates have been used to imply a mode of action of the root infecting *Fusarium* in SDS, these fail to fully reproduce all of the symptoms of SDS observed in plants. The organism appears compatible, and probably synergistic, with other microorganisms such as *Fusarium solani* fsp. *glycines*, and also with gram positive bacteria.

Possible Interactions with Glyphosate, Roundup, or Genetically Modified Crops

Increased severity of plant diseases after glyphosate is applied (Fig. 3) is well documented and, although rarely cited, the increased disease susceptibility is the herbicidal mode of action of glyphosate (Johal and Rahe,1988, 1990; Johal and Huber, 2009; Schafer et al, 2009, 2010). The loss of disease resistance in Roundup Ready® sugar beets when glyphosate was applied prompted researchers at the USDA sugar beet laboratory to include a precautionary statement in their paper, e.g. "Precautions need to be taken when certain soil-borne diseases are present if weed management for sugar beet is to include post-emergence glyphosate treatments" (Larson et al, 2006). Increased disease severity is documented from glyphosate applied 2-3 years previous to a primary crop (Fernandez et al, 2009).

Severe epidemics have occurred the past few years on our three major crops: wheat (take-all root and crown rot, Fusarium root and crown rot, Fusarium head blight and high mycotoxin concentrations), corn (Goss' wilt, Gibberella stalk rot, high mycotoxin concentrations), and soybean (sudden death syndrome - or SDS and Fusarium root rot) where weather conditions were favorable for disease. These diseases were especially pronounced under glyphosate weed management practices and/or with GMO crops. Many producers are finding that production of their primary crops has become unprofitable because of high disease incidence, yet there were isolated fields of non-GMO and non-glyphosate management within all of these areas where plants remained healthy and productive. These healthy fields had the same rainfall, temperature, and soil conditions as those adjacent severely diseased fields where GMO or glyphosate management practices were used.

Although most corn hybrids have been genetically resistant to Goss' wilt, preliminary research in 2010 demonstrated that the application of glyphosate herbicide or surfactants nullified this

resistance and rendered them fully susceptible to this pathogen (Figure 1). This disease was commonly observed in many Midwestern U.S. fields planted to RR corn in 2009 and 2010, while adjacent non-GMO corn with the same temperature, moisture and soil conditions had very light to no infections in spite of the high inoculum present in no-till crop residues (Figure 2). The increased Goss' wilt in 2010 was a major contributor to the estimated almost one billion bushels of corn 'lost' last year (based on USDA August estimated yields and actually harvested crop reported by USDA in January) in spite of generally good harvest conditions.

Caution Related to Roundup Ready Alfalfa

I requested that more research be conducted before GMO alfalfa was released because efficient production of alfalfa is dependent on genetic resistance to the ubiquitous bacterial wilt caused by *Clavibacter michiganense* subsp. *insidiosum*. This is a very closely related bacterium to *Clavibacter michiganense* subsp. *nebraskensis*, the cause of Goss' wilt of corn, where the application of surfactants (a common ingredient in glyphosate formulations) nullified resistance to this and other benign bacteria. Alfalfa is a major crop used for herbivores that currently have an increase in fetal losses of unknown cause. The suspect agent for these reproductive failures was found to be in high concentrations in Goss' wilt infected corn as well as sudden death syndrome (SDS) infected soybeans.

Thus, the loss of genetic resistance in Roundup Ready® corn hybrids to Goss' wilt (*Clavibacter michiganensis* subsp. *nebraskensis*) (Figs. 1, 2), synergistic relationship of the newly recognized electron microscopic organism causing infertility and abortions in animals with gram+ bacteria, and high populations of the new EM organism in RR corn leaves and silage creates a concern for the deregulation of Roundup Ready® alfalfa which is productive in many areas only because of its genetic resistance to bacterial wilt caused *by Clavibacter michiganensis* subsp. *insidiosum*. Increased susceptibility of alfalfa to bacterial blight could make alfalfa unprofitable for production and, if the EM organism is associated with it in alfalfa as it is in Goss' wilt infected corn, also unsafe for animal feed and their products such as milk for human consumption. The loss of alfalfa, the United State's most valuable forage crop for herbivore nutrition and fourth most economically important crop, could strike a mortal blow to struggling dairy and beef operations. The necessary research has not been done in these areas to justify the premature deregulation of Roundup Ready® alfalfa.

Interrelated health effects of glyphosate

Extensive research has shown that this potent tool for weed management, glyphosate, is also a strong immobilizer (chelator) of essential plant nutrients to impair nutrient uptake, translocation, and physiological efficiency at only a fraction of the labeled herbicidal rate (Eker et al, 2006; Ozturk et al, 2008; Cakmak et al, 2009; Zobiole et al, 2010; Jolly et al., 2004). Glyphosate is a powerful biocide to harm beneficial soil organisms important for nutrient recycling, N-fixation, nutrient availability, and natural disease control (Kremer & Means, 2009; Zobiole et al, 2010, 2010) with a resultant increase in diseases of corn (Fig. 2), soybeans (Fig. 3), wheat and other crops. The close relationship between mineral nutrition and disease severity is well documented (Datnoff et al, 2007). These effects of glyphosate can have deleterious effects on plant nutrition, disease susceptibility, and nutritional quality of the crop produced.

Deletarious effects of GM crops also are vividly demonstrated in reports from livestock producers in the U.S. Although some of these reports are anecdotal because of limited analytical

techniques to verify the cause, some producers have been able to resume economical operations by changing feed sources to non-GMO crops. Replicated independent research is needed in this area, especially in light of the serious toxicological concerns raised recently that show potential human and animal toxicity at very low levels of residual glyphosate in food/feed that are many times lower than permitted in U.S. food and feed products (Seralini et al., 2011). The recent Indian Supreme Court's independent analysis and Ruling that GMO eggplant posed a significant health risk to humans needs further evaluation in the U.S. (AgroNews, 2011).

Animal Reproductive Failure

The same, or similar organism, that has been seen in diseased plants and plant by-products is found in high concentrations in placental and other reproductive tissues, pig stomachs, manure, etc. At this time we do not know the full significance of the suspect agent, but it is imperative to investigate the agent further.

The suspect agent was first identified several years ago in aborted tissue from cattle, horse, and swine herds that were experiencing high reproductive failure rates in isolated areas in the United States. Increasing occurrence and severity of reproductive animal failure (infertility and spontaneous abortions) linked to this organism has been documented in numerous areas since then. High concentrations of this suspect agent have been confirmed in reproductive and aborted tissue from animals that have experienced infertility (cattle, swine, horses, poultry), pseudopregnancies (swine, horses), and spontaneous abortions (cattle, swine, horses). The organism was only discovered after all known causes of reproductive failure were ruled out, and a more in-depth evaluation was pursued. According to reports from farmers and veterinarians, the incidence of reproductive failure in livestock has increased in numerous locations in the US.

Physical Properties of the suspect agent

The organism was initially discovered by electron microscopic (EM) examination of aborted tissues at 38,000x magnification. At this magnification, it resembles a micro-fungus in morphology with small, spherical, catenulate sporulation from longer, flexuous filaments; however, this term is only descriptive of its appearance under the EM and does not describe it taxonomically. It does not appear to 'fit' any of the known taxons although we are awaiting results from molecular sequencing and other analyses for this purpose.

Culturing and Koch's Postulates Completed

Scientists can now culture the organism on several different media and have conducted Koch's postulates. It kills a chicken embryo in 24-72 hours after introduction, can be re-isolated, and cultured from this tissue for reinoculation into fertilized chicken eggs. Spontaneous animal abortions also have been induced in a controlled setting. Research is ongoing in this area.

A Scientists Responsibility

I feel I would be totally irresponsible to ignore my own research and the vast amount of published research now available that support the concerns we are seeing in production agriculture, without bringing it to the attention of the Secretary of Agriculture with a request for him to initiate the much needed independent research. Many producers can't wait an additional 3-10 years for someone to find the funds and neutral environment to conduct such critical research (Attachment 3).

Based on the scientific evidence currently accumulating, I do not believe it is in the best interests of the agricultural producer or consuming public for regulatory agencies to approve more GMO crops, particularly Roundup Ready® alfalfa and sugar beets, until independent research can establish their productivity when predisposed to potentially severe diseases, the irrelevance of the new EM organism, their nutritional equivalency, and their safety. In my letter, I asked the Secretary to allocate the necessary resources to do this, and requested that he exercise the utmost caution in deregulating these crops until such findings resolve the concerns expressed in the letter, if they do. There is an immediate need for both animal and plant research, and toxicology evaluation.

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Attachment 1: Letter to Secretary of Agriculture Thomas Vilsak

CONFIDENTIAL and URGENT

1/17/11

The Honorable Thomas Vilsack United States Secretary of Agriculture

Dear Secretary Vilsack:

A team of senior plant and animal scientists have recently brought to my attention the discovery of an electron microscopic pathogen that appears to significantly impact the health of plants, animals, and probably human beings. Based on a review of the data, it is widespread, very serious, and is in much higher concentrations in Roundup Ready (RR) soybeans and corn—suggesting a link with the RR gene or more likely the presence of Roundup. This organism appears NEW to science!

This is highly sensitive information that could result in a collapse of US soy and corn export markets and significant disruption of domestic food and feed supplies. On the other hand, this new organism may already be responsible for significant harm (see below). My colleagues and I are therefore moving our investigation forward with speed and discretion, and seek assistance from the USDA and other entities to identify the pathogen's source, prevalence, implications, and remedies.

We are informing the USDA of our findings at this early stage, specifically due to your pending decision regarding approval of RR alfalfa. Naturally, if either the RR gene or Roundup itself is a promoter or co-factor of this pathogen, then such approval could be a calamity. Based on the current evidence, the only reasonable action at this time would be to delay deregulation at least until sufficient data has exonerated the RR system, if it does.

For the past 40 years, I have been a scientist in the professional and military agencies that evaluate and prepare for natural and manmade biological threats, including germ warfare and disease outbreaks. Based on this experience, I believe the threat we are facing from this pathogen is unique and of a high risk status. In layman's terms, it should be treated as an emergency.

A diverse set of researchers working on this problem have contributed various pieces of the puzzle, which together presents the following disturbing scenario:

Unique Physical Properties

This previously unknown organism is only visible under an electron microscope (36,000X), with an approximate size range equal to a medium size virus. It is able to reproduce and appears to be a micro-fungal-like organism. If so, it would be the first such micro-fungus ever identified. There is strong evidence that this infectious agent promotes diseases of *both* plants and mammals, which is very rare.

Pathogen Location and Concentration

It is found in high concentrations in Roundup Ready soybean meal and corn, distillers meal, fermentation feed products, pig stomach contents, and pig and cattle placentas.

Linked with Outbreaks of Plant Disease

The organism is prolific in plants infected with two pervasive diseases that are driving down yields and farmer income—sudden death syndrome (SDS) in soy, and Goss' wilt in corn. The pathogen is also found in the fungal causative agent of SDS (*Fusarium solani* fsp glycines). **Implicated in Animal Reproductive Failure**

Laboratory tests have confirmed the presence of this organism in a wide variety of livestock that have experienced spontaneous abortions and infertility. Preliminary results from ongoing research have also been able to reproduce abortions in a clinical setting.

The pathogen may explain the escalating frequency of infertility and spontaneous abortions over the past few years in US cattle, dairy, swine, and horse operations. These include recent reports of infertility rates in dairy heifers of over 20%, and spontaneous abortions in cattle as high as 45%.

For example, 450 of 1,000 pregnant heifers fed wheatlege experienced spontaneous abortions. Over the same period, another 1,000 heifers from the same herd that were raised on hay had no abortions. High concentrations of the pathogen were confirmed on the wheatlage, which likely had been under weed management using glyphosate.

Recommendations

In summary, because of the high titer of this new animal pathogen in Roundup Ready crops, and its association with plant and animal diseases that are reaching epidemic proportions, we request USDA's participation in a multi-agency investigation, and an immediate moratorium on the deregulation of RR crops until the causal/predisposing relationship with glyphosate and/or RR plants can be ruled out as a threat to crop and animal production and human health.

It is urgent to examine whether the side-effects of glyphosate use may have facilitated the growth of this pathogen, or allowed it to cause greater harm to weakened plant and animal hosts. It is well-documented that glyphosate promotes soil pathogens and is already implicated with the increase of more than 40 plant diseases; it dismantles plant defenses by chelating vital nutrients; and it reduces the bioavailability of nutrients in feed, which in turn can cause animal disorders. To properly evaluate these factors, we request access to the relevant USDA data.

I have studied plant pathogens for more than 50 years. We are now seeing an unprecedented trend of increasing plant and animal diseases and disorders. This pathogen may be instrumental to understanding and solving this problem. It deserves immediate attention with significant resources to avoid a general collapse of our critical agricultural infrastructure.

Sincerely,

COL (Ret.) Don M. Huber Emeritus Professor, Purdue University APS Coordinator, USDA National Plant Disease Recovery System (NPDRS)

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Attachment 2. Letter from a Veterinarian

Hello, my name is _____. I am a veterinarian in Michigan.

I am working with a sow herd that has had elevated death loss for over two years and very poor reproductive performance for the last 6-8 months. I have done extensive diagnostics (primarily at Iowa State) and can find nothing infectious that is routinely found to explain the problem.

I suspect there is a toxin involved; I have done extensive testing on liver, feed, and water but can find no evidence of those compounds either. We have had a few individuals mention that the use of GMO crops could be contributing to these problems.

The producer recently saw your article to the secretary of agriculture and forwarded it to me. We are very intrigued by the organism you mention. Could you tell me if any laboratory is looking for this agent? How do we go about finding it? We are at the end of our rope and cannot figure this out. Any help you can give us would be greatly appreciated.

Attachment 3. Letter from 26 University Entomologists to EPA

Public Submission: EPA-HQ-OPP-2008-0836-0043. Docket EPA-HQ-OPP-2008-0836 Docket Title Evaluation of the Resistance Risks from Using a Seed Mix Refuge with Pioneer's Optimum AcreMax 1 Corn Rootworm-Protected Corn

Document EPA-HQ-OPP-2008-0836-0001; Public Submission EPA-HQ-OPP-2008-0836-0043 Public Submission Title Anonymous public comment Receipt Date 02/09/2009 Doc. Legacy ID EPA-HQ-OPP-2008-0836-0032(0900006480849377) Track No. 8084de39

General Comment

Comment The following statement has been submitted by 26 leading corn insect scientists working at public research institutions located in 16 corn producing states. All of the scientists have been active participants of the Regional Research Project NCCC-46 "Development, Optimization, and Delivery of Management Strategies for Rootworms and Other Below-ground Insect Pests of Maize" and/or related projects with corn insect pests. The statement may be applicable to all EPA decisions on PIPs, not just for the current SAP. It should not be interpreted that the actions and opinions of these 26 scientists represent those of the entire group of scientists participating in NCCC-46. The names of the scientists have been withheld from the public docket because virtually all of us require cooperation from industry at some level to conduct our research.

Statement:

"Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research. These agreements inhibit public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, its management implications, IRM, and its interactions with insect biology. Consequently, data flowing to an EPA Scientific Advisory Panel from the public sector is unduly limited."



Goss' wilt of maize



Figure 1. Effect of surfactants on Goss' wilt infection of Goss' wilt resistant maize hybrids.

Lesion index



Figure 2. A green non-GMO corn field (upper left) with premature dead and dying RR corn on two sides (upper right and bottom) heavily infected with Goss' wilt, 2010.



Figure 3. Healthy soybeans (left) where no glyphosate was applied in 2009 compared with severe SDS of the soybeans (right) where glyphosate was applied the Fall of 2009.