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Dr. Gregory L. Parham, Administrator
USDA-APHIS
1400 Independence Avenue, SW
Washington, DC 20205

Dear Dr. Parham,

The following material is presented as encouraged in your letter of May 2, 2011 wherein you responded to my January 17, 2011 letter to Secretary of Agriculture Thomas Vilsack alerting him to a large number of problems in production agriculture 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.

I appreciated the opportunity to meet with you, Dr. Woteki, and Dr. Kapps July 7. Thank you for the invitation extended in your May 2nd letter to 1) share information on the current crop and animal challenges that are threatening agricultural sustainability, 2) request reconsideration of deregulation of Roundup Ready alfalfa and other genetically engineered crops, 3) discuss information available on the 'new' electron microscopic organism that appears to be widespread, increasing in frequency, and impacting the health and productivity of both animals and plants, and 4) 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 ensure production efficiency and feed/food safety. Grant proposals are being prepared and the cooperation of USDA in the further research and documentation that is urgently needed of the serious agricultural production and health risks posed by GMO crops and the chemicals they are designed to tolerate will be welcome.

I have previously provided comments and documentation for the 2009 glyphosate review (Glyphosate 0178; EPA-HQ-OPP-2009-0361) and the more recent 2010 Roundup Ready Alfalfa Review. Since the public comment period for those reviews, there have been additional highly significant peer-reviewed published, scientific research on the safety and potential health risks associated with both GMO products and the glyphosate herbicide.

The leaking of my private letter to Secretary Vilsack to the public necessitated a further explanation of the concerns raised in the initial letter and this was released to the public on April 20 (attachment 1). The references presented here in no way should be considered an exhaustive listing of the scientific documentation for these concerns relevant to the deregulation of RR alfalfa and continued unregulated use of the herbicide glyphosate that is generically referred to as Roundup. The muzzling of USDA researchers, intimidation of academic scientists with research findings in these areas, and limited access to materials for

objective evaluation has greatly limited the critical information APHIS needs to make an objective and informed decision (Public submission, EPA-HQ-OPP-2008-0836-0043, 2009). Misleading marketing campaigns also have disarmed the general public and glyphosate users to the deleterious side effects of this popular chemical. Rather than reiterating the items already provided in the public comment submissions and April 20 explanation of my letter to Secretary Vilsack, I will briefly outline the concerns and supporting data that were raised in my letter as you have encouraged me to do in your letter of May 2, 2011.

The current crop and animal production environment is NOT normal and NOT sustainable! We are experiencing an escalating incidence of crop, animal, and human diseases, the emergence and reemergence of diseases once rare or under practical control, and new diseases previously unknown to science. There are published scientific studies documenting the intensification, and some times direct relationship, of these situations to genetically engineered (GMO) crops and/or the products they were engineered to tolerate. The wide spread epidemics experienced in recent years of Fusarium root rot and head blight of cereals, take-all of cereals, stalk rot and ear rots of corn, sudden death syndrome of soybeans, high mycotoxin levels in crops, and an increase in numerous other plant diseases are just a few examples of debilitating conditions recently experienced in production agriculture (Fernandez et al, 2005, 2007, 2008, 2009; Johal and Huber, 2009; US Wheat and Barley Scab Initiative, 2009, 2010). I am receiving reports of the wide-spread incidence of Goss' wilt of corn for the third year in a row.

The previously unknown cause of reproductive problems threatening the viability of animal production, presented by the American Cattlemen's Association on July 24, 2001 to the Senate Agriculture Committee (Anonymous, 2002), is consistent with information and characteristics of the 'newly' recognized electron microscopic sized organism and the impact of glyphosate and GMO crops that are becoming much clearer. The recent Indian Supreme Court finding (AgroNews, 2011) that commercial data submitted on the safety of genetically modified crops failed to meet internationally accepted standards for toxicological assessment highlights the need for independent, objective evaluation of this program for pest control. Although there is a significant body of critical research that has not been conducted in this regard, there is a growing list of scientific, peer-reviewed papers documenting serious safety issues with glyphosate at levels many times lower than permitted in the foods we consume and feeds fed our animals that are consistent with animal and human health and disease issues that are documented in practice (Antoniou et al, 2010, 2011; Aris and Leblanc, 2011; Benachour et al, 2007; Chainark, 2008; EFSA, 2007; Gasnier et al, 2009, 2010; Mazza et al, 2005; Paganelli et al, 2010; Pusztai and Bardocz, 2007, 2010; Ran et al, 2009; Schefers, 2011; Schubbert, et al, 1998; Seralini et al, 2009, 2010, 2011; Sharma et al, 2006; Tudisco et al, 2010; de Vendomois et al, 2009; Walsh et al, 2000).

My public comment for the Roundup Ready Alfalfa Review identified five major areas of research needed to assure sustainable crop production prior to deregulation of Roundup Ready® crops: 1) Study of the isogenic 'glyphosate-tolerant' cultivar with its non genetically engineered parent for nutrient uptake and translocation efficiency, changes in root exudates, nitrogen-fixation and nodulation, rhizosphere biological changes, yield, crop quality, and disease; 2) evaluation of the genetically engineered crop with and without the application of

glyphosate under several soil environments as above; 3) impact on subsequent crops in the rotation for establishment, nutrition, growth and productivity, disease, and crop quality; 4) degradation and persistence of glyphosate and its metabolites at the various depths encompassed by plant roots where it is deposited through root exudation; and 5) liability for bioremediation, detoxification of residual glyphosate, non-target effects, gene contamination and flow in the environment, increased vulnerability from loss of genetic diversity and 'buffering' against exotic threats.

These five areas of critical research needs are in addition to the need for proper genetic (Brown, 2000; McAfee, 2003), toxicological evaluation, and impact on feed and food safety. In the independent toxicological evaluation ordered by the Indian Supreme Court, the GM crop was deemed unsafe for human consumption and other deregulation applications were subsequently withdrawn. The 2009 French Supreme Court ruling that commercial claims of safety (biodegradability) of glyphosate constituted fraud are also note worthy. Differences in label claims for glyphosate in different countries reflect their more thorough understanding of the interactions of this commonly used herbicide on crop productivity and health factors than appear in the U.S.

Interactions of glyphosate impacting agricultural sustainability:

Interactions of glyphosate with plant nutrition and increased disease often have been overlooked, but become more obvious each year as glyphosate's residual effects become more apparent as a significant threat to agricultural sustainability (Yamada et al, 2009).

Glyphosate is a strong metal chelator that immobilizes essential plant nutrient elements (Bernards et al, 2005; Glass, 1984; Jolley et al, 2004; Lundager-Madsen et al, 1978; Martell and Smith, 1974; Motekaitis and Martell, 1985; Nilsson, 1985; Ptaszynski and Zwolinska, 2001; U.S. Patent Office, 1964) to reduce physiological efficiency and increase susceptibility of plants to disease (Bramhall and Higgins, 1988; Ganson and Jensen, 1988; Hornby et al, 1998; Keen et al, 1982; Johal and Rahe, 1984, 1988, 1990; Johal and Huber, 2009).

This broad-spectrum herbicide is also a very strong, but selective, biocide that inhibits and is toxic to many beneficial soil microorganisms responsible for plant nutrition and natural disease control, while stimulating soilborne plant pathogens and their synergists (Boyette, et al, 2006; Dick and Lorenz, 2006; Fernandez et al, 2005, 2006, 2008, 2009; Huber and McCay-Buis, 1993; Huber et al, 2005; Huber, 2010; Kremer and Means, 2009; Kremer et al, 2000, 2005; Lanen et al, 2009; Larson et al, 2006; Levesque and Rahe, 1992, 1993; Levesque et al, 1987; Liu et al, 1995, 1997; Lorenz et al, 2008, 2009; Means et al, 2007; Mekwatanakarn and Sivasithamparam, 1987; Motavalli et al, 2004; Sanogo et al, 2000, 2001; Smiley et al, 1992; Yang, 2010; Zobiolo et al, 2010).

Mineral nutrients function in plant metabolism and as plant constituents, and there is a close relationship of mineral nutrient sufficiency with disease resistance (Datnoff et al, 2007; Englehard, 1989; Huber, 1980; Huber and McCay-Buis, 1993; Huber and Haneklaus, 2007; Johal and Huber, 2009). As a strong micronutrient chelator, glyphosate reduces the physiological efficiency, uptake, and translocation of manganese and other essential nutrients

in the plant and seed (Bellaloui et al, 2009; Cakmak et al, 2009; Gordon, 2007; Eker et al, 2006).

It is the strong chelating ability of glyphosate that makes it a broad-spectrum herbicide by inhibiting enzymes such as EPSPS in the shikimate pathway and other enzymes (Ganson and Jensen, 1998) that are important for plant resistance to soilborne pathogens (Rahe et al, 1990; Schafer et al, 2009, 2010). **Thus, glyphosate's herbicidal mode of action is through increased disease susceptibility** (Rahe and Johal, 1984, 1988; Rahe et al, 1990; Schaffer et al, 2009, 2010). Genetically engineered plants that are tolerant of glyphosate contain the bacterial EPSPS-II gene and various other genes to maintain some tolerance to the soilborne fungal pathogens that kill normal plants.

Plants genetically engineered to contain the EPSPS-II bacterial gene are less efficient in the uptake and utilization of micronutrients even in the absence of glyphosate that adds an additional stress on the plant and produces a 'yield drag' (Benbrook, 1999; Dodds et al, 2002; Gordon, 2006, 2007; Zobiolo et al, 2010e). Since there is nothing in the glyphosate-tolerant plant that affects the chelation of micronutrients by glyphosate, the application of glyphosate also reduces the uptake, utilization, and bioavailability of micronutrients to impair photosynthesis, water use efficiency, amino acid metabolism, nodulation, nitrogen fixation, and nutrient value of Roundup Ready® plants (Hernandez et al, 1999; King et al, 2001; Purcell et al, 2000, 2001; Reddy et al, 2000; Zobiolo et al, 2010a, b, c, d, e, f, g, h, 2011a, b, c).

Glyphosate is systemic in the plant, accumulates in meristematic tissues (growth points and reproductive structures), and is exuded from roots into the soil to damage adjacent or subsequent crops (Coupland and Caseley, 1979; Kremer et al, 2005; Reddy et al, 2003, 2004; Rodrigues et al, 1982). The strong chelating ability of glyphosate with mineral nutrients, and absorption in clay lattices (Farenhorst et al, 2009), inactivates glyphosate in most soils; however, this chelating detoxification may take several days or weeks and the chelated compound may persist in soil for a considerable time to be desorbed later as an active compound damaging to plants and microbes. The French Supreme Court ruled in 2009 that claims of biodegradation of glyphosate (as contained in the U.S. label) constituted fraud.

Glyphosate residues in seed and plant tissues significantly damage seed germination and subsequent plant growth (Barker, 2010) as well as produce a toxicological hazard for animals and humans (Antoniou et al, 2010, 2011; Benachour et al, 2007; Chainark, 2008; EFSA, 2007; Gasnier et al, 2009, 2010; Mazza et al, 2005; Paganelli et al, 2010; Pusztai and Bardocz, 2007, 2010; Ran et al, 2009; Schefers, 2011; Schubbert, et al, 1998; Seralini et al, 2009, 2010, 2011; Sharma et al, 2006; Tudisco et al, 2010; de Vendomois et al, 2009; Walsh et al, 2000). Dr. Hanna Mathers, Ohio State University, has documented that glyphosate can accumulate in perennial plants for years. Glyphosate can drift during application and soil residues can be desorbed and damage adjacent or subsequent crops in the rotation at extremely low concentrations (Bott et al, 2011; Eker et al, 2006; Farenhorst et al, 2009; Laitinen et al, 2005; Neumann et al, 2006; Tesfamariam et al, 2009).

Reduced Nutrient Quality

Mineral nutrients are not only essential for plant growth and function, but plants are also the source of minerals essential for animal and human nutrition. **Glyphosate significantly reduces the content and bioavailability of mineral nutrients in feed and food** (Bellaloui et al, 2009; Bott et al, 2008; Cakmak et al, 2009; Gordon, 2006; Zobiolo et al, 2010b, d, g) to create functional mineral deficiencies in plants, animals and people fed the low mineral-available plant constituents. Glyphosate residues in feed and food products could also directly reduce mineral bioavailability on ingestion of this strong mineral chelator (Barker, 2010). Transmission of the gene from feed to animals is a well-documented phenomena with unknown consequences (Brown, 2000; Chainark, 2008; EFSA, 2007; McAfee, 2003; Pusztai and Bardocz, 2007, 2010; Ran et al, 2009; Schubbert et al, 1998, Seralini et al, 2009, 2010, 2011; Sharma et al, 2006; Tudisco et al, 2010). **Thus, residual glyphosate in seed, and gene transfer (flow) in feed, food, and the environment constitute serious production and toxicological concerns for food and feed safety.**

There has been a growing incidence of disease in animal production programs (especially cattle, dairy, and swine) associated with low manganese or other micronutrients. Manganese is essential for proper liver function and deficiencies are associated with increased infectious diseases in general, bone and tissue deformities, reproductive failure, and death (Dunham, 2010). Cakmak (2009) reported a 45 % reduction of manganese, iron, and other essential nutrients in Roundup Ready soybean seed when plants were treated with glyphosate. The reduced bioavailability and content of manganese and other micronutrients in feed and food grown under glyphosate weed control programs has led to an increased need for mineral supplementation in animal rations. Veterinarians have documented manganese deficiency in new beef and dairy herds this year in Northern Iowa even though educational programs have been alerting producers to the increased need for supplementation. Loss estimates of dairy replacement heifers at birth are now 8-11 %, with the primary cause generally attributed to poor manganese uptake or excess selenium (Dunham, 2011; Schefers, 2011).

There is a serious lack of research on effects of glyphosate (Roundup®) on the production, diseases, nutritive value or chemical residues with Roundup Ready alfalfa. Glyphosate is known to affect all of these factors negatively. Alfalfa, a legume, is our fourth most important agricultural crop and is produced in all of the states; however, it's profitable production is dependent on efficient fixation of atmospheric nitrogen through the symbiotic relationship with soil bacteria (*Rhizobiaceae*) and genetic resistance to another plant pathogenic bacterium, *Clavibacter michiganense insidiosum*. A general decline in nitrogen fixation of beans, lentils, peas, and soybeans has been observed since the introduction of glyphosate herbicide. The application of glyphosate to leguminous plants inhibits nitrogen fixation in two ways: 1) glyphosate translocated to weed or RR crop root tissues and in root exudates is toxic to the *Bradyrhizobium*, *Rhizobium*, and other soil-borne bacterial species in the soil that are associated with root tissues that synergistically fix nitrogen for the plant to use physiologically for amino acid and protein synthesis (Zablotowicz and Reddy, 2007; Zobiolo et al, 2010 a, h, 2011) and 2) by physiologically immobilizing both nickel and manganese in root tissues that are required by the bacterial and plant enzymes involved in nitrogen fixation (Purcell et al, 2000; Purcell, 2001; Zobiolo et al, 2010a, b, 2011). A consequence of reduced nitrogen fixation is lower production efficiency and low nutritive

value (amino acid and protein content) for animal or human food. Reduced N, P, K, Ca, Mg, S, B, Cu, Fe, Mn, and Zn have been found in Roundup Ready alfalfa compared with normal alfalfa, and lower nutrient content of soybeans and corn are also reported (Bellaloui et al, 2009; Bott et al, 2008; Cakmak et al, 2009; Eker et al, 2009; Gordon, 2006; Ozturk et al, 2008; Zobiolo et al, 2010b, d, g) to contribute to the increased disease, infertility, and reproductive failure in animals that is being commonly observed unless supplemental minerals are supplied in the ration to compensate for the reduced levels in crops produced under glyphosate and or GMO weed management practices.

Profitable alfalfa production was very limited until genetic resistance to the wide-spread *Clavibacter michiganense insidiosum* causing bacterial wilt was developed. This organism occurs world-wide and is an extremely damaging pathogen of non-resistant alfalfa. Research in 2009 and 2010 demonstrated the loss of genetic resistance of Roundup Ready corn hybrids to Goss' wilt (*Clavibacter michiganense nebraskensis*), a very closely related bacterium and disease to alfalfa bacterial wilt, when the surfactant or glyphosate formulations were applied directly to the plant. Goss's wilt, a previously very localized and limited disease, has occurred in epidemic proportions in wide-spread areas of the Midwest the past two years and has already been diagnosed in broad areas of Iowa this year. The loss of genetic disease resistance, productivity, and reduced nutrient value could strike a mortal blow to struggling U.S. dairy and beef operations dependent on this most valuable forage for herbivores. The newly recognized electron microscopic-sized organism causing reproductive failure in animals has been prolific in Goss' wilt infected corn to raise serious concerns for the safety of glyphosate treated Roundup Ready® alfalfa.

New electron microscopic-sized 'organism' causing infertility and miscarriage in animals.

There has been a noticeable increase in reproductive failure and fetal losses in the Midwestern U.S. since 1998-2000, just a few years after the introduction of Roundup Ready® crops and the subsequent increase in glyphosate useage and exposure. This entity was only discovered after exhaustive searches for the cause of infertility, pseudopregnancies, and miscarriage (spontaneous abortions) that could not be attributed to any other known cause of these reproductive failures in animals. It now threatens the viability of cattle, dairy, equine, swine, and poultry production (Anonymous, 2000; Scheffeer, 2011). It is estimated that as high as 10-11 % of producers are experiencing this problem with some being forced into bankruptcy or switching to crop production because of it. The frequency of reproductive failure is increasing in all animal species.

After ruling out all previously known causes of reproductive failure, and a thorough and exhaustive search for the etiologic agent, a very small suspect agent was identified in 1998 in aborted placenta and fetal tissue with an electron microscope at 38,000 X magnification. The organism was eventually isolated and cultured on a defined agar medium – initially in conjunction with larger microorganisms such as gram positive bacteria – and later in pure culture. Pure culture inoculum was then used to test Koch's postulates to establish this organism as the etiologic agent causing reproductive failure. It can prevent pregnancy, kill a fertilized egg early to produce a pseudopregnancy, or induce a mid- to late term miscarriage

later in pregnancy. Injection into a fertilized chicken egg for instance, kills the developing embryo within 24-48 hours. Detailed examination of aborted (miscarried) fetuses and placenta for the newly recognized organism has shown its presence in all of the cases examined to date. In animals, it has been identified in placental tissue, amniotic fluid, fetal tissue, stomach contents, semen, eggs, manure of several animal species, and milk from dairies feeding distillers protein.

An intense search for the inoculum source for animal infection led the scientists to soybean meal in the animal ration as a major source of the organism. It occurs in high populations in soybeans -, especially if infected with sudden death syndrome (SDS) caused by the soil-borne fungal plant pathogen, *Fusarium solani* fsp. *glycines*. The organism has been identified in the mycelium of this *Fusarium* species that infects the roots of soybean plants, and subsequently in leaves and seed of plants symptomatic for SDS. The organism has been observed in soil; fungal mycelia; soybean leaves, seed and meal; various corn tissues – especially those with Goss' wilt; 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. Animal miscarriages have been identified from IA, IL, KY, MI, MO, NE, ND, SD, and WI.

Characteristics of the 'organism:'

The organism is very small and is seen only with a transmission or scanning electron microscope at 25,000-50,000 magnification. It is pleomorphic depending on the media and environment, varying from small spore-like entities to filamentous growths appearing to originate from the somewhat small spherical bodies. Cultural characteristics under the EM resemble mold growth with filamentous and spore-like growths produced. It can be cultured on defined agar media and produces both general forms of growth depending on the media and environment. High energy X-ray analysis (XRF and XANES mapping) of concentrated growth removed from an agar media surface showed a generally uniform mineral composition consisting of (in decreasing order) iron, zinc, potassium, manganese, and a small amount of calcium generally evenly distributed throughout the amorphous mass analyzed, typical of living material. This 'organism' does not appear to 'fit' into any of the known taxons although we are awaiting results from molecular sequencing and other analyses for this purpose.

Potential interactions of the 'new' organism with glyphosate:

Increased severity of plant diseases after glyphosate is applied is well documented and, although rarely cited, 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 planting a cereal crop (Fernandez et al, 2005, 2007, 2009). Glyphosate also increases the severity of *Fusarium* diseases in other crops in the rotation (Fernandez et al, 2008).

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 epidemic areas where plants remained healthy and productive. These healthy fields had the same rainfall, temperature, and soil conditions as those adjacent to 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. 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. Severe infection by Goss' wilt is already reported from wide-spread areas of the Midwest this year. 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.

The excessive use of glyphosate, encouraged by RR crops and further development of glyphosate-resistant weeds (Gaines et al, 2010; Johnson et al, 2009), is a major contributor to the increased severity and epidemics of plant and animal diseases, reduced nutrient quality, high mycotoxin levels, and toxic chemical residues we are experiencing in production agriculture. The glyphosate-GMO-weed management system has not been adequately researched for safety, equivalency, or sustainability (Brown, 2000; McAfee, 2003).

As you suggested in your May 2, 2011 letter, I reviewed the Roundup Ready® alfalfa EIS for deregulation and was unable to locate peer-reviewed scientific papers justifying deregulation of RR alfalfa. In as much as the genetically engineered RR alfalfa is not 'substantially equivalent' to its non-GMO parent (Brown, 2000; McAfee, 2003) or determined safe through peer-reviewed scientific study, I urge your reconsideration of the decision to deregulate Roundup Ready alfalfa based on the principle of 'Scientific Precaution' until essential research can be completed relative to its safety, equivalency, and sustainability.

Sincerely yours,

Don M. Huber
Professor Emeritus, Purdue University

CC: Dr. Woteki, Under Secretary, Chief Scientist USDA

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