Message

From: THOMAS B KLEVORN
Sent: 6/1/1999 12:56:23 PM
To: DONNA R FARMER
Subject: Re[5]: Questions about Glyphosate

Donna,

Thanks for the additional information. With the exception of a few minor events, things are going pretty well here from a transition perspective. The kids are settling into their new school and we are developing a better understanding of how things work in SPO. It's quite an adventure!

Tom

_____ Reply Separator _____
Subject: Re[4]: Questions about Glyphosate
Author: DONNA R FARMER at MONSL125
Date: 5/31/99 1:55 PM

Tom,

Your welcome. Life is always busy....work/home/work/home...the key is the balance!!!!

Regarding business....unfortuantely we feel that Hardell is just the tip of the iceberg for these type of "association epi" studies. We have his two papers with NHL and hairy cell leukemia and one from a Canadian Ag Health study that declares an association between glyphosate and miscarriages and pre-term deliveries.

What is of greater concern however is an American initiative called the AHS.

The AHS stands for Agricultural Health Study - a large multi-faceted epidemiologic study being conducted by scientists with the National Cancer Institute (NCI), the EPA, The National Institute for Environmental Health Sciences (NIEHS). It is its 7th year of data collection and soon will publish results linking specific pesticides to various health effects. These organizations believe that farmers and their families are suffering from a variety of illinesses and that these illinesses are caused by pesticides....no bias there!

The widespread and ever growing use of glyphosate caused the AHS investigators to reevaluate and give more priority to glyphosate.

It is a prospective study of 90,000 farmers and their families in Iowa and North Carolina. The primary purpose of the study is to look for associations between pesticides and human health effects.

Many groups have been highly critical of the study as being a flawed study, in fact some have gone so far as to call it junk science. It is small in scope and the retrospective questioneer on pesticide usage and self reported diagnoses also from the questioneer is thought to be unreliable...but the bottom line is scary...there will be associations identified between glyphosate use and some health effects just because of the way this study is designed.

Therefore we are working thru the ACPA here to do an exposure study...using glyphosate in the pilot (if the pilot goes well it will expand into a full study) with a similar group of farmers to get a handle on exposure in order to better help us prepare ourselves for when the publications come out similar to those of Hardell.

We feel it is really important to network with the epi experts in

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TRIAL EXHIBIT 220

Case No. 3:16-cv-0525-VC

Date Entered _____

By _____
Deputy Clerk

Europe and then back here in the US before the AHS publications break, we were in the process of coordinating this when the Hardell study hit the press...it pushed up our timeline and had us switch from first networking in the US to EU.

Regarding family - [redacted]

Don't hesitate to let me know if you need any additional info on Hardell or help on something else.

Best regards,

Donna

_____ Reply Separator
_____ Subject: Re[3]: Questions about Glyphosate
Author: THOMAS B KLEVORN at monspo01 Date: 5/31/99 1:15 PM

Donna,

Many thanks to you and your team for the prompt reply. This information is very helpful to us.

I hope all is going well with you and your family these days. I am sure you are busy with them AND this sort of thing!

Tom

_____ Reply Separator _____
Subject: Re[2]: Questions about Glyphosate
Author: DONNA R FARMER at MONSL125
Date: 5/28/99 6:24 PM

All,

We have been working this issue from a variety of fronts.

What has been done..what are we doing..?

Letters:

- a letter has been written and sent to the editors of Cancer by John Acquavella, Mark Cullen. and me on Hardell's NHL paper (see attached letter.doc). Our letter has been accepted for publication and should be published in about 2 months.

- John Jackson has co-authored a letter with two outside experts and that has been submitted to the editor of the New Scientist(see attached newsci~1.doc)

Technical Reviews:

- John A. has done technical reviews of Hardell's papers.
  a final detailed critique of the Non-Hodgkins Lymphoma (NHL) paper

by Hardell (see attached critique.doc)

a draft of a detailed critique on another paper by Hardell and collegues (Nordstrom is the lead author on this) regarding hairy cell leukemia mentioning glyphosate. Hardell refers to these findings in his paper on NHL. (see attached nordst~1.doc)

ECPA - IVT initiatives to engage Hardell:

- An industry group IVT in Sweden has requested to meet with Hardell. At his request they sent him a letter with suggested dates to meet with him. They have not heard a reply from him yet. This meeting could be used as a cover to see what Hardell is up to without highlighting Monsanto's issues. We are tracking this and will have Monsanto people attend if and when this meeting goes.

History, Networks and Engagements:

- Monsanto has a long and very bad history with Hardell (if you would like a summary of this let me know and I will forward it). We are planning on meeting with Hardell - if he will meet with us but it is imperative that we approach him in such a way that we don't make things worse for ourselves. Therefore John Acquavella. and I have been working with an expert, Vince Covello, in crisis and risk communication on how we do that. Dr. Covello has been evaluating Monsanto and helping us understand how we got ourselves in the mess we are in...by our messages, how we have engaged/treated people etc. .

- We (John A, myself and John Cowell) are targeting July to go to Europe to engage Hardell and meet with epidemiologists all over Europe that will be receptive to us and our science.

- John Acquavella has already contacted a prestigious European epidemiologist from Greece to help us coordinate this initiative. This expert as well as another collegue of his from Sweden have joint appointments at the Harvard School of Public Health in Boston. They are very interested in working with us on this initiative as they feel that Hardell's work does not meet the standards that they feel should be there for their field of work. We plan to meet with them in June.

Our request:
Please send John and I a copy of the article that was written in Brazil. It will help us help you prepare a better response if we can see what was actually said. Please don't hesitate to let us know what else we can do to help.

Donna and John

_____ Reply Separator _____
Subject: Re: Questions about Glyphosate
Author: STEPHEN J WRATTEN at MONSL125
Date: 5/28/99 4:12 PM

Luis

There has been quite a bit of activity about the Hardell paper you mention, and Monsanto has developed a scientific review as well as Questions and Answers. I will send several email separately which will answer most of your questions. I have asked John Acquavella, our epidemiology expert, to email you his review as I lack an electronic copy. I will fax a copy of the paper and the Q&As to 55 11 817 6254.

Basically, the study looked at cancer patients and non-cancer patients and asked them (or their surviving relatives) whether they had used various pesticides. The paper was not about glyphsoate, but that was merely one of many correlations they looked at. It was published int ehJournal "Cancer" and later reviewed in "New Scientist". Out of 404 cancer patients, 4 reported using glyphosate. Out of 1145 non-cancer patients, 3 reported glyphsoate use. From these numbers, it appears that glyphsoate use is correlated with cancer. However, the total number using glyphosate is very very low, so that 1 or 2 people make the difference. Letters have been written by Monsantoto Cancer and to New scientist, and our scientists are attempting to visit Hardell in Sweden. He is known to have ill will toward Monsanto from earlier issues with 2,4-D.

Yes Glyphsoate is registered and used in Sweden.

There is a second paper by the same author on "hairy cell leukemia" with similar findings, and I have also forwarded you our review of that one.

Regarding your second question, the key to answering this is the fact that glyphosate salts are totally dissociated in solution. (We have a report to show this, which I will mail). Because they are totally dissociated, the anion (glyphsoate) and the cation (IPA, ammouium, etc) migrate separately in biological systems. Since biological fluids and soil waters contain much larger amounts of other dissociated ions (sodium, potassium, etc.) these switch freely (equillibrate) with the glyphosate ions, no matter which form is initially delivered. Therefore, no matter whether glyphosate acid or a salt form is used, the substance in the biological system is the same, and the result should also be the same.

I do not believe there are side-by-side comparison studies of effects and behavior for acid and salt forms. It has been reasoned from chemical principals, that when small amounts of a chemical are placed into environmental systems, the intrinsic pH buffering capacity of the soil or biological fluids neutralize the acid to form a salt. If a salt is introduced, the ions exchange freely, forming the same equillibrium mixture as if the acid had been used.

It is impractical to redo these long regulatory studies on each salt form because several are marketed, so the core studies are conducted on acid in support of any completely dissociated salt form. This is standard regulatory practice among Japan, Europe, and US for acidic active ingredients such as dicamba, 2,4-D, etc. The formation of a salt should be considered as a formulation step, which is merely done to facilitate the preparation of a commercial product, in the same way that stabilizers, ph buffering agents, and carriers are added to all formulations to facilitate their commercial use.

It is incorrect to say that all the environmental fate studies were conducted with the acid. The laboratory studies are generally conducted with radiolabeled acid, but teh field studies were conducted with Roundup Formulation. The leaching results from field studies using formulations are completely consistent with the labortory findings using acid. That is, glyphsoate binds tightly to soil and degrades in place to AMPA and then to other natural materials. These studies, taken together, describe the environmental fate picture, and it is not necessary to rely solely on studies with acid to understand the environmental fate of formulations.

I need to leave right now, but when I return on Tue, I will mail and fax the supporting information. I have been unable

to get the fax to send the Hardell paper to you this afternoon, but will try again on Tur 1-Jun.

Steve

Marian and Donna, have you other arguments to add to these comments?

_____ Reply Separator _____

Subject: Questions about Glyphosate
Author: LUIS R FAVORETTO at MONSP001
Date: 5/28/99 1:53 PM

Steve

We have two problems to be solved involving Glyphosate, and we need again your help. I would like to request you a promptly answer for both, since it is extremely important for us.

The subjects involve Glyphosate and there is no relation between them, one is a answer to an article in the newspaper and the second one is a formal requirement from our environmental agency (IBAMA). Casually both question occured at the same time.

- The first one is about a publication in a newspaper talking about a study done in Sweden, as text below.

"Lennart Hardell, the Orebro Medical Center, and Mikael Eriksson,Lund University , Sweden, published a study showing the relation between pesticides and the increase of up to 73% in determined types of cancer, such as lymphomas (non-hodgkins).

The exposure of the persons victimized by this disease was 2.7 times above the average healthy persons in the case of MCPA (a widely used herbicide) 3.7 times in the case of several fungicides and 2.3 times in case of Glyphosate. This is the same herbicide to which the genetically modified soybean seeds are resistant and which were recently granted authorization by the Brazilian Agriculture Ministry to be planted and commercialized. According to the researchers, these chemicals can suppress immunity and facilitate the way to viruses and bacteria."

The question is, how reliable is this report? What is our position on this? Can we get a copy of that report?

By the way, is Glyphosate registered in Sweden?

- The summary below will give you an idea about our problem with IBAMA. As I said above this is an official requirement, and we will have to give them an official answer. We have also to consider the possibility of our answer be supported by a meeting with Monsanto toxicologists and IBAMA technical group.

These are relevant questions concerning to different studies accomplished for both, technical and formulated product. Studies of acute toxicity have been related for technical and formulated products in salt and acid form. However, for studies of behavior in soil and chronic toxicity tests, only the acid form was used.

Regarding to plant behavior can be explained by Glyphosate metabolism, which transform it in acid form. These information are mentioned in

many references.

It is necessary to get information about metabolism, biotransformation and kinetic in soil, in water and in humans which could justify chronic studies only in acid form. For this reason, we request your assistance to elucidate the following questions:

a- The Glyphosate behavior in acid form and salt is similar in plants, soil,water and human?

b- If different, which were the criteria used to select only the acid form to perform the chronic and soil behavior studies with Glyphosate?

c- Though the salt and acid forms have different solubility, dissociation and reactivity, which were the criteria used to extrapolate mobility data, adsorption, biodegradability and behavior in humans from acid to salt?

If you need more details, please let me know.

Thanks in advance for your support.

Best regards.

L.R.G.Favoretto