Message

From: SCHRADER, SHAWN [AG/1630] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=538369]

1/22/2015 3:57:39 PM Sent:

EDWARDS, JEAN A [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=152055]; WILTS, MIKE E To:

> [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=16109]; JOHNSON, GLENN M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=161205]; SEIFERT-HIGGINS, SIMONE [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=546720]; DE WILDE, ANNEMIEKE [AG/1000]

[/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ADEWI];

GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=527246]

SCHNEIDER, TIMOTHY L [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=133403]; TRASER-CC:

SCHMALZ, SHERI E [AG/1630] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=117539]

Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Thanks Jean and Mike for follow up and closure. Thanks to the team for the support.

From: DE WILDE, ANNEMIEKE [AG/1000] Sent: Thursday, January 22, 2015 8:39 AM

To: EDWARDS, JEAN A [AG/1630]; GOLDSTEIN, DANIEL A [AG/1000]

Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ,

SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000]

Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Jean,

Thank you for bringing closure to this employee report!

Annemieke

"Better health is better performance in all you do" — What are you doing for your health today?

Annemieke De Wilde, MD, MPH, FACOEM

Office: 314-

Mobile: 314

E-mail: annemieke.de.wilde@monsanto.com

Location: LS1029 Mailstop: LS1A

From: EDWARDS, JEAN A [AG/1630]

Sent: Thursday, January 22, 2015 6:44 AM

To: EDWARDS, JEAN A [AG/1630]; GOLDSTEIN, DANIEL A [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]

Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ,

SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000]

Subject: RE: 2014 Annual Adverse Effects Reporting Notification

To All,

I spoke with the retired employee yesterday and explained that his report has been reviewed by

by the Monsanto medical director and epidemiologist (I explained what that was), then sent to the adverse effects team.

I told him that we had gathered his work history and chemicals he would have been exposed to here. These were reviewed and

they have not determined an association between his medical condition and the chemicals

he would have worked with here at the plant.

He did not seem to have any further questions or concerns, but I asked him to contact me if he had any questions or concerns in the future or would like to speak with anyone else.

Thanks to all for your assistance in addressing this matter,

Jean

From: EDWARDS, JEAN A [AG/1630] Sent: Tuesday, January 20, 2015 2:41 PM

To: GOLDSTEIN, DANIEL A [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]

Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ,

SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000]

Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Dan,

Thank you for your response and for your assistance with this. I spoke to Annemieke and I will be following up with

the individual by phone to let him know that his report has been reviewed.
I would like Mike Wilts to sit in on the conversation and he is out of the plant today, so we'll try to
make the call tomorrow. I'll let you know how the call is received and if any remaining questions or concerns.
Jean
From: GOLDSTEIN, DANIEL A [AG/1000] Sent: Tuesday, January 20, 2015 12:19 PM To: DE WILDE, ANNEMIEKE [AG/1000]; EDWARDS, JEAN A [AG/1630] Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; SEIFERT-HIGGINS, SIMONE [AG/1000] Subject: RE: 2014 Annual Adverse Effects Reporting Notification
Annemieke and Jean-
I agree with the Adverse Effects Committee that there is no FIFRA(6)a2 report needed for glyphosate or other active ingredients at this time.
With no clear allegation or specific association, I do not believe there is a TSCA 8(e) reporting issue either.
QUESTIONS:
Is there any OSHA reporting requited for this illness? I do NOT believe that there is a need to report, but I am not generally involved in the OSHA reporting and it has been a very long time since I have been involved. I just want to make sure the issue has been considered.
Finally- I assume that there is a desire to follow up with the individual who made the original inquiry. I am happy to participate in any communications. Do you have any sense of whether you want this to be in written form, personal communication via phone (or both) and who else should be in the conversation? Obviously Occ

Med and Site safety (and possibly HR) may want to be involved or at least be aware and may wish to be a part of any verbal communication.
Please let me know how the plant/ESH/Occ-Med wants to move forward on communications. Happy to help any way necessary.
Dan
From: DE WILDE, ANNEMIEKE [AG/1000] Sent: Wednesday, December 10, 2014 7:49 PM To: GOLDSTEIN, DANIEL A [AG/1000] Cc: WILTS, MIKE E [AG/1630]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ SHERI E [AG/1630]; JOHNSON, GLENN M [AG/1000]; VICINI, JOHN L [AG/1000]; FARMER, DONNA R [AG/1000]; EDWARDS, JEAN A [AG/1630] Subject: Re: 2014 Annual Adverse Effects Reporting Notification
Mike,
Once you and Glen have had a chance to review the exposure data, let's reconvene to discuss communicating back to Adverse Effect committee and to talking points for Jean Edwards).
What is your thoughts on getting back to via Jean?
If you agree, what are your comments on proposed talking points:
- your concern has been forwarded to the adverse effect committee, literature does not show any significant workplace exposures
- we are checking on your exposure history
- we will review all data to see if your personal HC leukemia experience can possibly add to the scientific knowledge base.
I have included Jean in CC.

Happy to discuss by phone too
Annemieke De Wilde - Sent from my iPhone
On Dec 10, 2014, at 14:37, "GOLDSTEIN, DANIEL A [AG/1000]" <
Please see attached Medline search for hairy cell leukemia. This is a small body of literature and there do not appear to be any well established links between occupational exposures and hairy cell leukemia.
Previously reported chemical specific associations (which have not been borne out by further studies) include the triazine herbicides as reviewed by Sathiakumar et al (this was a Monsanto funded study if I recall correctly), glyphosate (discussed below), and some very weak allegations around solvents and benzene.
The glyphosate allegations by Hardell are very weak, and in a much larger study (the Ag Health Study from the US National Cancer Institute- the largest study of its type) this association was not found.
There are some broad associations with pesticide categories, including herbicides and organophosphate insecticides.
At this point, it would be worth looking for an exposure history for various pesticide active ingredients, as this would likely include glyphosate, triazine, and possibly 2,4-D depending on his role and on the production at Muscatine (we sell a glyphosate/2,4-D product- but not sure where it is formulated). The organic solvent connection appears very weak, but it would be worth assessing potential ongoing benzene exposure as this has been a topic of discussion in the literature. I am not aware of routine benzene exposure at Muscatine- bat cannot say I have ever looked into the matter specifically.
I am not suggesting that finding any of these esposures would indicate a causal relationship- only that we need to follow up with the patient at some point and that we need to understand exposures to have an intelligent conversation around the reported associations.

Dan

From: WILTS, MIKE E [AG/1630]

Sent: Friday, December 05, 2014 9:07 AM

To: ADVERSE, EFFECTS [AG/1000]

Cc: SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630];

GOLDSTEIN, DANIEL A [AG/1000]; JOHNSON, GLENN M [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]

Subject: FW: 2014 Annual Adverse Effects Reporting Notification

Adverse effect committee,

I am forwarding you this email chain regarding a comment received by our plant nurse in Muscatine. Dr. Goldstein, Glenn Johnson and Dr De Wilde recommend that I send this to you for review. They are currently reviewing additional information for Hairy Cell Leukemia.

If you have any questions please feel free to contact me

Michael E. Wilts, ASP

Industrial Hygienist

Monsanto Muscatine

Phone: 563

Cell: 563-

Fax : 563-

<u>ଅmonsanto.com</u>

From: GOLDSTEIN, DANIEL A [AG/1000] Sent: Thursday, December 04, 2014 8:42 AM

To: JOHNSON, GLENN M [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]; FARMER, DONNA R [AG/1000]

Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L

[AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]

Subject: RE: 2014 Annual Adverse Effects Reporting Notification

This goes back to the allegation/publication by Hardell et al, specifically related to glyphosate exposure and Hairy Cell leukemia. This has not held up to further examination, but obviously the work exposure history is key.

I should be able to look at this. My long string of travels is over, and other than a trip on Dec 9/10 this month is pretty sedate.

Dan

From: JOHNSON, GLENN M [AG/1000]

Sent: Wednesday, December 03, 2014 4:38 PM

To: GOLDSTEIN, DANIEL A [AG/1000]; DE WILDE, ANNEMIEKE [AG/1000]

Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L

[AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]

Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Mike.

I agree with sending to the committee for review as Dan said below.

Most of the sources I looked at (Mayo Clinic, NCI, Medline Plus, Leukemia and Lymphoma Society, Hairy Cell Leukemia Foundation, Leukemia and Lymphoma Research (UK) and Lymphoma Association (UK)) echoed what Jean had found. Most said the cause or risk factors of hairy cell leukemia are not known.

The Hairy Cell Leukemia Association (US) linked to the U.S. Department of Veterans Affairs' Agent Orange information.

Getting the work history sounds like a good idea, but before you spend a lot of time trying to figure out his exposure profile I think it would be helpful to get some more specific guidance on what chemical(s) we should be targeting, if any. Dan and Annemieke, I don't know if you have time to look at this when you return or if some of the toxicologists would be able to give some specific guidance.

Best regards,

Glenn M. Johnson, CIH, ROH

Phone: 314-Fax: 314-Cell: 314

glenn.m.johnson@monsanto.com

From: GOLDSTEIN, DANIEL A [AG/1000] **Sent:** Wednesday, December 03, 2014 1:11 PM

To: DE WILDE, ANNEMIEKE [AG/1000]

Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; JOHNSON, GLENN M [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]

Subject: RE: 2014 Annual Adverse Effects Reporting Notification

Agree- could be TSCA 8e if not active or formulated pesticide- do send on to reporting committee and we will follow up.

Dan

From: DE WILDE, ANNEMIEKE [AG/1000]
Sent: Wednesday, December 03, 2014 1:09 PM

To: GOLDSTEIN, DANIEL A [AG/1000]

Cc: WILTS, MIKE E [AG/1630]; SHELTON, PAUL E [AG/1000]; JOHNSON, GLENN M [AG/1000]; SCHRADER, SHAWN [AG/1630]; SCHNEIDER, TIMOTHY L [AG/1630]; TRASER-SCHMALZ, SHERI E [AG/1630]; EDWARDS, JEAN A [AG/1630]

Subject: Re: 2014 Annual Adverse Effects Reporting Notification

I agree that this is not an allegation. In previous lives, the companies kept this on file. If similar "stories surface" the combination of stories may make it an allegation subject to TSCA 8(c).

My advice is to report it to the adverse events team as an FYI, not as a formal allegation report. They will know what to do with it.
Annemieke
Annemieke De Wilde - Sent from my iPhone
On Dec 3, 2014, at 12:52, "GOLDSTEIN, DANIEL A [AG/1000]" <
This is not reportable in my opinion because he did not make an allegation of relatedness but rather asks a question.
I am not suggesting we ignore the issue or fail to respond to the employee- just saying that as currently worded this would not trigger 6(a)2 report. On the road today- will follow up with further information. Dan
Sent from my iPhone
On Dec 3, 2014, at 10:53 AM, "WILTS, MIKE E [AG/1630]" <@monsanto.com > wrote:
Dan, Paul, Glenn and Annemieke,
I was requested to look into this by Muscatine's plant manager. This comes from a retiree that is working currently as a contractor for Monsanto. He saw the adverse effects notice and sent this to Jean Edwards our plant nurse. She has done some research (since I was on vacation) and found that this type of cancer is related to age and gender vs. chemical exposure. I have gone to HR to see if they can pull up employment records and will look at exposure records for the areas that he worked in during those periods of time. I am forwarding this to you to find out your opinions. Thank you in advance.
Best regards,
Michael E. Wilts, ASP
Industrial Hygienist
Monsanto Muscatine

Phone: 563-

Cell

Fax : 563-

@monsanto.com

From: EDWARDS, JEAN A [AG/1630]

Sent: Wednesday, December 03, 2014 9:34 AM

To: WILTS, MIKE E [AG/1630]

Subject: FW: 2014 Annual Adverse Effects Reporting Notification

From: [AG-Contractor/1000]
Sent: Monday, November 24, 2014 7:54 AM

To: EDWARDS, JEAN A [AG/1630]

Subject: FW: 2014 Annual Adverse Effects Reporting Notification

Jean,

I have been diagnosed with Hairy Cells Leukemia. You may or may not remember that I had irregular blood counts before I retired. I don't know if this diagnosis

Is related to working around all of the chemicals that I may have been exposed to at Muscatine.

I don't know if it has anything to do with the message below so I am sending you this as information only.

Regards,

From: ADVERSE, EFFECTS [AG/1000] **Sent:** Friday, November 21, 2014 3:24 PM

Subject: 2014 Annual Adverse Effects Reporting Notification

To Monsanto Employees:

NOTICE: Pursuant to Monsanto Company's obligations under several laws, all Monsanto employees are receiving this email regarding the procedure for notifying the appropriate internal personnel about potential adverse effects of our commercial and research products. As described in this notification, it is your responsibility as an employee to report any such effect if you become aware of it. Thank you for your attention to this important matter.

This annual notification is for all Monsanto employees who could come into possession of either: (a) information regarding alleged or actual "adverse effects" from conventional, biological, or biotechnology-based pesticide products currently or previously registered by Monsanto Company; or (b) information which suggests a conclusion of "substantial risk of injury to health or the environment" relating to non-pesticide "chemical substances," which includes most chemicals and even certain recombinant microorganisms. For pesticide products, the information may be related to the active ingredient (chemical or protein) itself, or any component of the product including inerts, safeners, metabolites, contaminants and degradation products.

The United States Environmental Protection Agency (U.S. EPA) and other international regulatory agencies require the reporting of this information under certain circumstances. If you become aware of information which suggests a conclusion of "adverse effect" or "substantial risk," you must immediately forward that information to the Adverse Effects Reporting Committee as instructed below. The information may originate inside or outside of the United States.

The types of information which may be reportable include, but are not limited to, the following:

- (a) Results from scientific studies
- (b) Allegations of injury to human or animal health
- (c) Environmental contamination
- (d) Allegations of damage from off-target movement (e.g. drift, run-off)

For more information, Adverse Effects Reporting CBTs can be taken through Monsanto University.

IMPORTANCE:

Monsanto has reporting obligations under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or Toxic Substances Control Act (TSCA). Under these laws, Monsanto may be considered to be in possession of adverse effect information when the information becomes known to any employee or agent of Monsanto, and timelines for Monsanto to report to the relevant agency can be short. Failure of an employee to report the required information to the Adverse Effect Reporting Committee in a prompt fashion can result in civil and/or criminal penalties against Monsanto or the employee and cancellation or suspension of a product.

REPORTING:

It is not your responsibility to determine if the information you possess is reportable to the U.S. EPA or other agencies. It is, however, your responsibility to notify the Adverse Effects Reporting Committee if you believe the information *might be* reportable under the provisions of the laws mentioned above. When received, the information will be reviewed and, if appropriate, an official report will be submitted by the Adverse Effects Reporting Committee to the relevant agencies according to the reporting guidelines. We encourage you also to discuss the information with your supervisor.

If you have questions regarding information you possess, please contact the Adverse Effects Reporting Committee through one of the following:

- Simone Seifert-Higgins
- By phone: (314)
- By Outlook address: ADVERSE, EFFECTS [AG/1000]
- By: e-mail address: effects.adverse@monsanto.com

Subject: Notificacion annual sobre el reporte de consecuencias adversas 2014

Para los empleados de Monsanto:

AVISO: De acuerdo con las obligaciones de Monsanto Company conforme a varias leyes, todos los empleados de Monsanto están recibiendo este correo electrónico en relación con el procedimiento para notificar al personal interno adecuado sobre las posibles consecuencias adversas de nuestros productos comerciales y en investigación. Como se describe en esta notificación, como empleado tú eres responsable de reportar cualquiera de estas consecuencias, si llegas a darte cuenta de ellas. Gracias por tu atención a este importante asunto.

Esta notificación anual es para todos los empleados de Monsanto que puedan entrar en posesión de: (a) información sobre "consecuencias adversas" presuntas o reales de productos pesticidas convencionales, biopesticidas, o pesticidas basados en biotecnología, registrados anterior o actualmente por Monsanto Company; o (b) información que sugiera una conclusión de "riesgo considerable de lesión a la salud o al medio ambiente", en relación con "sustancias químicas" no pesticidas, que incluye a la mayoría de los productos químicos e incluso algunos microorganismos recombinantes. Para los productos pesticidas, la información puede relacionarse con el ingrediente activo (sustancia química o proteína) por sí solo, o cualquier componente del producto incluyendo inertes, protectores, metabolitos, contaminantes y productos de degradación.

La Agencia de Protección Ambiental de Estados Unidos (U.S. EPA, por sus siglas en inglés) y otros organismos reguladores internacionales requieren que se reporte esta información bajo determinadas circunstancias. Si llegas a darte cuenta de información que sugiera una conclusión de "consecuencia adversa" o "riesgo considerable", debes remitir tal información de inmediato al Comité de Reporte de Consecuencias Adversas, tal como se explica a continuación. La información puede originarse dentro o fuera de los Estados Unidos.

Los tipos de información que pueden ser reportables incluyen, entre otros, los siguientes:

- a) Resultados de estudios científicos
- b) Reclamos de daños a la salud de seres humanos o animales
- c) Contaminación ambiental
- d) Reclamos por daños como resultado de la movimiento fuera del objetivo de aplicación (ej. deriva o escorrentía)

Para obtener más información puedes tomar Capacitación Basada en Computadora (Computer Based Training o CBT) sobre reporte de consecuencias adversas a través de la Universidad Monsanto.

IMPORTANCIA:

Monsanto tiene obligaciones de reportar sobre consecuencias adversas conforme a las disposiciones del Acta Federal relativa a los insecticidas, fungicidas y raticidas (FIFRA, por sus siglas en Inglés) o el Acta sobre control de sustancias tóxicas (TSCA, por sus siglas en Inglés). De acuerdo a estas leyes se puede considerar que Monsanto está en posesión de información sobre consecuencias adversas cuando cualquier empleado o agente de Monsanto tiene conocimiento de la información, y los plazos para que Monsanto lo reporte al organismo pertinente pueden ser breves. La omisión por parte de un empleado de reportar con prontitud la información requerida al Comité de Reporte de Consecuencias Adversas, podrá acarrear sanciones civiles y/o penales contra Monsanto o el empleado, y la cancelación o suspensión de un producto.

NOTIFICAR:

No es tu responsabilidad determinar si la información que posees es reportable a la U.S. EPA o a otros organismos. No obstante, es tu responsabilidad notificar al Comité de Reporte de Consecuencias Adversas si crees que la información puede ser reportable conforme a las disposiciones de las leyes mencionadas más arriba. Una vez que se reciba, la información se analizará, y si corresponde, el Comité de Reporte de Consecuencias Adversas presentará un informe oficial a las agencias pertinentes, de acuerdo con las pautas para reportar. Te animamos también a platicar sobre esta información con tu supervisor.

Si tienes preguntas sobre la información que posees, ponte en contacto con el Comité de Reporte de Consecuencias Adversas a través de alguno de los siguientes medios:

- Simone Seifert-Higgins
- Por teléfono: (314)
- Por la dirección de Outlook: ADVERSE, EFFECTS [AG/1000]
- Por: dirección de correo electrónico: effects.adverse@monsanto.com

<hairy cell leukaemia.docx>