

From: Smith, James JM SC-CSP
Sent: Monday, November 25, 2002 7:04 AM
To: Briggs, Barnaby D SC-CSEA
Cc: Tholstrup, Susan C SCC; Clegg, Patsy M SCC-CHSE-PC; Sullivan, Nancy E SCC-CBAR; Walls, Chuck G SCC-CHSE; Dammann, Angelika A SC-CSEA
Subject: RE: Benzene Health study
Barnaby

Thanks. I have amended the draft below on the basis of some of what you told me and in order to make it a bit more crisp -- eg we should not say 'an enhancement would be...'. If such an enhancement is needed then we shld say we are doing it. Also I thought it was March 2001 that we decided to go ahead, not September.

If we are handling this as an issue, do we have issue management papers including qs and as?

I think this may provoke some qs to which I hope we have answers; Do we trade much benzene into China? Are the worker and public exposure standards satisfactory? I have presumed some answers below. But grateful if you can have this confirmed.

Plse confirm to me that we will circulate all the issues to country organisations and not just those on the top level matrix. Plse write me the procedure note on how this will be done and how we will inform those invloved about this procedure

Grttl if we cld discuss once more so we can finalise. I will finalise this together with you and Susan.

I will want to copy this to Ek Kia b4 we send. I am not really clear on how much involvement Nick will confrim he has had

James

Updated draft reply:

Malcolm

With regrets fro the delay, set out below are the answers to the questions you raised on the benzene study in Shanghai:

Ethics

The study covers individuals who had already been identified by Shanghai medical authorities as having a potentially benzene exposure related condition. Each has agreed that their case be included as data in the study, on the basis of explanations provided to them. Consent forms signify agreement. The study itself is of course not creating new benzene exposures.

The study was conducted in Shanghai because the medical records and exposure data are extensive and well organised. The basis exists for a sound scientific study which the authorities support both in principle and with storng technical capability. There is no reason from an ethical point of view that the study could not have been conducted in Europe or the USA. The choice was based on availability of data. We considered the possibility that the individuals in China might have had less real freedom of choice about use of their records. However we believe that due process can be demonstrated.

We considered if the study could provoke discussion about poor practice on exposure management for benzene in China. We believe that a study of this kind is consistent with our

continuing efforts to ensure high and consistent risk management practices globally.

More generally, before committing to the study, we considered its issues management aspects. We are satisfied that, both from the points of view of the product itself and from the point of view of developing country workers, the study can stand scrutiny. We began consideration of this study in November 2000. In addition to our own HSE, product stewardship and issues management people, the discussion included Nick Wood in China, Xaiowei Liu, Jeremy Frearson and several others in PX and OP.

The study is not on our top level issues management matrix. However it is listed second on our next level HSE list as a 'Potential Global Issue'.

Country organisation/ Issues system

I regret to say, we did not explicitly inform the country chair about this study and did not follow up in the letters process for 2001 to make sure he was notified. We will enhance our procedures on issues notification to countries to ensure this error does not recur (this will involve the procedure itself, its communication and quality assurance for execution).

However as noted above, while we did not inform Ek Kia directly, the China country organisation was involved before the study began as were PX and OP. But there is now a difference in view as to whether we actually gave the confirmation to the country organisation that the study was to go ahead. We will take the learning from this too and ensure we achieve closure on the discussion of a study of this kind.

James Smith
CSP

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Internet: <http://www.shell.com>

-----Original Message-----

From: Briggs, Barnaby D SC-CSEA
Sent: 24 November 2002 21:25
To: James Smith (E-mail)
Cc: Tholstrup, Susan C SCC; Clegg, Patsy M SCC-CHSE-PC; Sullivan, Nancy E SCC-CBAR; Walls, Chuck G SCC-CHSE; Angelika Dammann (E-mail)
Subject: RE: Benzene Health study
Importance: High

James

Malcolm Brinded's questions were:

(1) Whilst I understand this study has been cleared by an external ethics committee, even so, would the study be 100% permissible if conducted in the US today? My concern is that we should not lay ourselves open to accusations that we are 'exposing developing country workers to risk that would be unacceptable elsewhere?'

2) I asked Ek Kia to what extent the China Country organisation had been involved in agreeing this programme before it went ahead. Answer - basically not. My concern here is

to note this is a little reminiscent of the Animal Testing Issue - i.e. where our involvement in a Joint Industry Project that goes international can all too easily leave our relevant Country organisation out of the loop (and at best, unable to leverage the positives from such research sponsorship, at worst, exposed to unexpected criticism). This one may already have been instigated before the animal testing issue came up, but even so, have we now got the generic learning in place?

1) **Ethics**

The study covers individuals who have already been identified by Shanghai hospitals as having a benzene exposure related condition, and who are willing and fully informed volunteers. The study itself is not exposing anyone to benzene, rather it uses these volunteers and exposure records that have been collected by local regulatory authorities, who are fully involved in the work. This fact, in addition to the ethics panel, the patients' treatment and the legacy of the medical facilities in Shanghai, reassures me that the accusation above would not hold water.

2) **Issues system**

Nick Wood was involved in the discussions on this issue that Chemicals co-ordinated from in November 2000 - the decision was taken to participate in September 2001. These discussions also included Xaiowei Liu, Jeremy Frearson, and several others in PX and OP. This study is currently on the Chemicals HSE issues list as a "Potential Global Issue", and has been for at least all this year - it has never been escalated to the overall Chemicals issues matrix.

Country Chairs and Country Coordination Teams should be made aware of Chemical issues as early in the process as possible. As issues are put on the Chemicals Global Issues List, the affected country external affairs representative and the lead Chemical person in that country should be notified promptly by a Chemicals external affairs representative. Chemical's Global Issues List will continue to be reviewed on a routine basis. An improvement to this process would be that the same notification system should apply for all HSE issues which are regarded as having the potential to become global issues.

I hope that these points address the questions that Malcolm had, but please let me know if any more detail is required.

Barnaby

-----Original Message-----

From: Tholstrup, Susan C SCC
Sent: Friday, November 22, 2002 1:53 PM
To: Briggs, Barnaby D SC-CSEA; Clegg, Patsy M SCC-CHSE-PC; Sullivan, Nancy E SCC-CBAR; Walls, Chuck G SCC-CHSE
Subject: RE: Benzene Health study
Importance: High

Barnaby,

Per my voice mail, we seem to have multiple people chasing down the same rabbit. We have a draft to the questions that have been listed below and have had one review from Chuck. I will forward that draft to you.

To get the communication process back "under control", I would suggest that we work the information back through you and you give the one answer back to James.

Nancy/Chuck if you have a concern about that, please let me know.

thanks,
Susan

-----Original Message-----

From: Briggs, Barnaby D SC-CSEA
Sent: Friday, November 22, 2002 5:00 AM
To: Clegg, Patsy M SCC-CHSE-PC; Sullivan, Nancy E SCC-CBAR; Walls, Chuck G SCC-CHSE; Tholstrup, Susan C SCC
Cc: Smith, James JM SC-CSP; Dammann, Angelika A SC-CSEA
Subject: FW: Benzene Health study
Importance: High

James has asked me to draft him a note for Malcolm addressing the two questions set out below in Malcolm's note this morning. I will copy you in on that note.

While I am happy setting out the issues process that was and is being followed in this case, I would appreciate your guidance on the ethical question. I have some papers which I have yet to go through in detail, all of which seem to point to a satisfactory answer, but I would find any further notes and guidance on the question very helpful. I need a simple straightforward point (e.g. "Yes this study would be more than acceptable in the US today"), backed up with some facts (e.g. ethics discussions and committees).

Many thanks

Barnaby

-----Original Message-----

From: Smith, James JM SC-CSP
Sent: Friday, November 22, 2002 10:26 AM
To: Briggs, Barnaby D SC-CSEA
Subject: FW: Benzene Health study

Barnaby

As promised

James

James Smith
CSP

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-----Original Message-----

From: Smith, James JM SC-CSP
Sent: 22 November 2002 08:10
To: Brinded, Malcolm A SI-MGDMB; Willems, Rein R SC-CX
Cc: Tan, EkKia EK SCHINA-CH
Subject: RE: Benzene Health study

Malcolm

Thanks. Understand and appreciate your questions and had received them per your filenote following your recent visit. Have been assembling the answers and rechecking our systems re issues and Country Chairs. I'm intending that you get a response from me early next week.

I regret we did not inform the country chair correctly on this study. And even though this study started pre the animal testing issue response, we missed the opportunity in the letters process for 2001 to pick it up. That's what I'm working on at the moment and will cover in my reply.

James

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-----Original Message-----

From: Brinded, Malcolm A SI-MGDMB
Sent: 22 November 2002 03:19
To: Willems, Rein R SC-CX; Smith, James JM SC-CSP
Cc: Tan, EkKia EK SCHINA-CH
Subject: RE: Benzene Health study
Importance: High

Rein, james

Many thanks for the details provided. I recognise this is a significant piece of research with high standards of ethics considerations and monitoring. But.....the two questions I have in mind are :-

(1) Whilst I understand this study has been cleared by an external ethics committee, even so, would the study be 100% permissible if conducted in the US today? My concern is that we should not lay ourselves open to accusations that we are 'exposing developing country workers to risk that would be unacceptable elsewhere?'

2) I asked Ek Kia to what extent the China Country organisation had been involved in agreeing this programme before it went ahead. Answer - basically not. My concern here is to note this is a little reminiscent of the Animal Testing Issue - i.e. where our involvement in a Joint Industry Project that goes international can all too easily leave our relevant Country organisation out of the loop (and at best, unable to leverage the positives from such research sponsorship, at worst, exposed to unexpected criticism). This one may already have been instigated before the animal testing issue came up, but even so, have we now got

the generic learning in place?
Regards
Malcolm

-----Original Message-----

From: Willems, Rein R SC-CX
Sent: 19 November 2002 19:11
To: Brinded, Malcolm A SI-MGDMB; Tan, EkKia EK SCHINA-CH
Cc: Smith, James JM SC-CSP
Subject: FW: Benzene Health study

Malcolm, I understand that the note below(sent earlier) was only part of the answers you sought. My apologies for sending you this incomplete. James will complete this with the requested info.

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-----Original Message-----

From: Willems, Rein R SC-CX
Sent: Tuesday, November 19, 2002 2:33 AM
To: Brinded, Malcolm A SI-MGDMB; Tan, EkKia EK SCHINA-CH
Cc: Smith, James JM SC-CSP; Walls, Chuck G SCC-CHSE; Sullivan, Nancy E SCC-CBAR
Subject: Benzene Health study

Malcolm, EkKia
Please find below an update of a study on Health effects of Benzene on workers in Shanghai in which Shell Chemicals via a consortium of various U.S. Benzene producers is involved. As you can see the study on long term health effects is coordinated by U.S. and China universities(Fudan in Shanghai) with the full cooperation of the Shanghai Municipal health authorities.
The results are expected in 2007.
Shell is one of the participants and we support this study as part of our product stewardship work.
If you do have any further questions pls. let us know.

<< File: Shanghai Benzene Health Study - CMD Update - Nov 14.doc
(Compressed) >>

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