

Message

**From:** WRATTEN, STEPHEN J [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=119523]  
**Sent:** 4/5/2002 5:33:26 PM  
**To:** HEALY, CHARLES E [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=297008]; GUSTIN, CHRISTOPHE [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=83930]; GARNETT, RICHARD P [AG/5040] [/O=MONSANTO/OU=EA-5040-01/cn=Recipients/cn=107838]; FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]; BROECKAERT, FABRICE [AG/5040] [/O=MONSANTO/OU=EA-5040-01/cn=Recipients/cn=591489]; LI, ABBY A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=194179]; MARTENS, MARK A [AG/5040] [/O=MONSANTO/OU=EA-5040-01/cn=Recipients/cn=21606]; KRONENBERG, JOEL M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=501517]; JACOBS, ERIK [AG/5040] [/O=MONSANTO/OU=EA-5040-01/cn=Recipients/cn=296512]; MCKENNA, RUTH M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=226168]  
**CC:** HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; MCKENNA, RUTH M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=226168]  
**Subject:** RE: TNO dermal penetration studies

*The integrity of the skin samples is only one aspect to be checked. As Joel mentioned, any technical rechecking should start with the test material and the ability to dissolve the radioactive portion to a homogeneous test sample and to dispense it as expected.*

*If we are not dropping the issue completely, then I for one would like to see the chromatograms that demonstrate that the radioactive component in the testing solutions is pure (as expected) and co-elutes with authentic glyphosate standard. Further, a series of radioactive counting experiments that show that a known and expected amount of radioactivity can be dispensed from the test solutions and recovered from the test system reproducibly and with excellent accountability, and properly quantified by the radioactivity determinations.*

Steve

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

**From:** HEALY, CHARLES E [AG/1000]  
**Sent:** Friday, April 05, 2002 9:44 AM  
**To:** GUSTIN, CHRISTOPHE [AG/1000]; GARNETT, RICHARD P [AG/5040]; FARMER, DONNA R [AG/1000]; BROECKAERT, FABRICE [AG/5040]; LI, ABBY A [AG/1000]; MARTENS, MARK A [AG/5040]; KRONENBERG, JOEL M [AG/1000]; WRATTEN, STEPHEN J [AG/1000]; JACOBS, ERIK [AG/5040]; MCKENNA, RUTH M [AG/1000]  
**Cc:** HEYDENS, WILLIAM F [AG/1000]; MCKENNA, RUTH M [AG/1000]  
**Subject:** RE: TNO dermal penetration studies

I agree entirely. I, too, understood that TNO was going to recheck the technical aspects of the test with rat skin and that that was all we agreed would be done at this point in time. Without a clear understanding of what happened, I see no way we could or should move forward with any other work at the moment.

Chuck

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

**From:** GUSTIN, CHRISTOPHE [AG/1000]  
**Sent:** Friday, April 05, 2002 8:57 AM  
**To:** GARNETT, RICHARD P [AG/5040]; FARMER, DONNA R [AG/1000]; BROECKAERT, FABRICE [AG/5040]; LI, ABBY A [AG/1000]; HEALY, CHARLES E [AG/1000]; MARTENS, MARK A [AG/5040]; KRONENBERG, JOEL M [AG/1000]; WRATTEN, STEPHEN J [AG/1000]; JACOBS, ERIK [AG/5040]; MCKENNA, RUTH M [AG/1000]  
**Cc:** HEYDENS, WILLIAM F [AG/1000]; MCKENNA, RUTH M [AG/1000]  
**Subject:** RE: TNO dermal penetration studies

Shouldn't TNO at least try to find out what caused these unexpected results? We are left behind with too many questions after all this. I thought they offered to recheck their system and redo the rat-skin test on their own expense. If so I don't really see why we would not accept that. I'm sure the triallate and inert folks and (Abby and Chuck) will agree.

regards,  
Christophe

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

**From:** GARNETT, RICHARD P [AG/5040]  
**Sent:** Friday, April 05, 2002 12:46 AM  
**To:** FARMER, DONNA R [AG/1000]; BROECKAERT, FABRICE [AG/5040]; GUSTIN, CHRISTOPHE [AG/1000]; LI, ABBY A [AG/1000]; HEALY, CHARLES E [AG/1000]; MARTENS, MARK A [AG/5040]; KRONENBERG, JOEL M [AG/1000]; WRATTEN, STEPHEN J [AG/1000]; JACOBS, ERIK [AG/5040]; MCKENNA, RUTH M [AG/1000]  
**Cc:** HEYDENS, WILLIAM F [AG/1000]  
**Subject:** RE: TNO dermal penetration studies

Donna

We dropped the programme for glyphosate because a further study was not likely to help us meet the project objective:

> we initiated the studies from a regulatory angle to help meet the requirements for operator exposure, given that the Annex I end point for dermal absorption for glyphosate was set at 3%, which we believed was a high value based on a weight of evidence approach.

> the results of the rat skin studies show levels of absorption for glyphosate of a similar order to the Annex I end point; also confirm our expectation that surfactant concentration affects the dermal absorption

> therefore, from the regulatory angle, there is no point in pursuing the studies further (even though it would be interesting to show that the unusual results on a few skin samples were an artifact of the experimental work)

> given that we need to do additional studies on triallate it seems a sensible use of budget and of TNO's time to replace the glyphosate studies with additional work on triallate

regards richard

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

**From:** FARMER, DONNA R [AG/1000]  
**Sent:** Thursday, April 04, 2002 7:25 PM  
**To:** BROECKAERT, FABRICE [AG/5040]; GUSTIN, CHRISTOPHE [AG/1000]; LI, ABBY A [AG/1000]; HEALY, CHARLES E [AG/1000]; MARTENS, MARK A [AG/5040]; KRONENBERG, JOEL M [AG/1000]; WRATTEN, STEPHEN J [AG/1000]; JACOBS, ERIK [AG/5040]; MCKENNA, RUTH M [AG/1000]  
**Cc:** HEYDENS, WILLIAM F [AG/1000]; GARNETT, RICHARD P [AG/5040]  
**Subject:** RE: TNO dermal penetration studies

Fabrice,

For clarification - a decision was made to not repeat the rat skin study and to stop any further dermal penetration studies with MON 35012 with and without surfactant - correct? Are any other glyphosate-based formulations going to be tested? Or has the whole program been dropped?

Donna

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

**From:** BROECKAERT, FABRICE [AG/5040]  
**Sent:** Thursday, April 04, 2002 5:39 AM  
**To:** GUSTIN, CHRISTOPHE [AG/1000]; LI, ABBY A [AG/1000]; HEALY, CHARLES E [AG/1000]; MARTENS, MARK A [AG/5040]; KRONENBERG, JOEL M [AG/1000]; FARMER, DONNA R [AG/1000]; WRATTEN, STEPHEN J [AG/1000]; JACOBS, ERIK [AG/5040]; MCKENNA, RUTH M [AG/1000]  
**Cc:** HEYDENS, WILLIAM F [AG/1000]; GARNETT, RICHARD P [AG/5040]  
**Subject:** TNO dermal penetration studies  
**Importance:** High

Dear all,

Thanks for the good discussion we had on dermal penetration issues. Please find below the main actions which have been decided:

**Glyphosate:**

Although we agreed to repeat the *in vitro* dermal penetration study with rat skin as proposed by TNO, we came to the conclusion that the penetration of glyphosate would have been [probably] greater than the 3% already imposed by the German authorities. We decided thus to **STOP** the study (effective today morning).



[REDACTED]

[REDACTED]

Regards, Fabrice