Message

From: JACKSON - GHEISSARI, AMELIA ELIZABETH [AG/1920] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AEJACK196E]

Sent: 4/6/2016 1:46:01 AM

To: REBMAN, JOHN [AG/1000] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JREBMc1a]

CC: CARPINTERO, DAVID [AG/5040] [/O=MONSANTO/OU=EXTernal (FYDIBOHF25SPDLT)/cn=Recipients/cn=c07f6e0161a14529901f8b80678f6b2f]; MURPHY, STEPHANIE L [AG/1920] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SLMURPc64]; RAMSAY, JONATHAN [AG/5040] [/O=MONSANTO/OU=EA-5041-01/cn=Recipients/cn=61249]; HEERING, DAVID C [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=RECIPIENTS/cn=68681]; AGUSTIN, MELISSA [AG/1000] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MRAGUS]; PLEYSIER, ANNICK [AG/5040] [/O=MONSANTO/OU=EA-5041-01/cn=Recipients/cn=620789]; GARNETT, RICHARD P [AG/5040] [/O=MONSANTO/OU=EA-5041-01/cn=Recipients/cn=107838]; MURPHEY, SAMUEL [AG/1000] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SMURP]; HIDE, ALISTAIR [AG/6042] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AHIDEef7]; VORUZ, NATALIA [AG/6042] [/O=MONSANTO/OU=EA-5040-01/cn=Recipients/cn=NNVORU]; JENKINS, DANIEL J [AG/1920] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=813004]

Subject: Re: French Embassy visit

Hi David

Redacted

Best wishes. Amelia

On Apr 5, 2016, at 5:20 PM, REBMAN, JOHN [AG/1000] <[redacted]> wrote:

Privileged and Confidential

David, all,

Redacted

-John

From: CARPINTERO, DAVID [AG/5040]
Sent: Tuesday, April 05, 2016 3:51 PM
To: JACKSON - GHEISSARI, AMELIA ELIZABETH [AG/1920]; MURPHY, STEPHANIE L [AG/1920]
Cc: RAMSAY, JONATHAN [AG/5040]; HEERING, DAVID C [AG/1000]; AGUSTIN, MELISSA [AG/1000]; PLEYSIER, ANNICK [AG/5040]; GARNETT, RICHARD P [AG/5040]; MURPHEY, SAMUEL [AG/1000]; REBMAN, JOHN [AG/1000]; HIDE, ALISTAIR [AG/6042]
Subject: RE: French Embassy visit

Amelia, Stephanie,

Please, find here some background information on this issue in France affecting formulations of glyphosate that contain tallowamine.
A briefing to the your visitors from the French embassy could help to drive a clarification with the French regulator ANSES before it becomes irreversibly entrenched.
Please find below some background and a set of messages prepared with Richard and Annick.

We are expecting the letter of intention from French regulator ANSES very soon, and it might point to "imminent health risk" regarding the use of tallowamine.
We do not agree with the withdrawal but we will abide. We simple would need the argumentation for the ban/withdrawal to not be based on "human health" but other on considerations like precautionary principle.
The consequences of this ban if referring to human health risks have the potential to go beyond France and would potentially have global and trade impact. It is therefore of essence that any intention to ban does not refer to imminent human health risk.

Please let Richard or me know if you have any question.

Best regards,
David

Background:

- French regulator ANSES informally informed Monsanto and others that they will send a "letter of intention" to withdraw Glyphosate products containing polyethoxylated tallow amine (POEA-t) surfactant, with a period of 15 days to comment. This letter is imminent but not yet received. Further, it appears that ANSES will justify this intention to withdraw referring to imminent health risks.
- In its review of Glyphosate published 9 Feb 2016, ANSES concluded that it would "conduct an immediate re-assessment of the products containing glyphosate and tallowamine." https://www.anses.fr/en/system/files/SUBCHIM2015sa0093EN.pdf
- ANSES has not published the results of this re-assessment but the decision to withdraw products is disappointing because it is not based on an assessment of all the available data.
- We understand that it is based on the conclusions of the EFSA evaluation published 12 Nov 2015. This states that EFSA did not have the possibility to review the original data for most of the end points, and identifies data gaps including the submission of original toxicity studies on POEA-t, as well as clarification of certain other issues. Industry has not been requested, yet, to provide the available studies and information. There are tox studies on tallowamine available that have not been requested by authorities. EFSA was unable to conclude on a risk assessment without these. http://www.efsa.europa.eu/en/efsajournal/pub/4303.
- It is, therefore, very disappointing that ANSES has reached its decision without consideration of the available studies and information, and without releasing its re-assessment.

Proposal:

1. Monsanto does not agree with but will not challenge the removal of tallowamine based Glyphosate products from the market
2. Due to the incomplete assessment, it is proposed that the withdrawal of products from the market reflects a "precautionary approach" (i.e. not a direct risk to health and safety).
3. The consequences of the positioning of the withdrawal need to be considered carefully because of other approved uses in other fields, including personal care and hygiene consumer products. Logically, if the ban is due to an immediate risk to health and safety issue, these other uses should be banned at the same time.

Key messages:

- We learned that ANSES is planning to send a "letter of intention" to withdraw Glyphosate products containing polyethoxylated tallow amine (POEA-t) surfactant in the coming days to individual registrants.
- We understand that the intention to withdraw would be justified based on imminent health risks, and that it is based on the conclusions of the EFSA evaluation published 12 Nov 2015.
    1. This states that EFSA did not have the possibility to review the original data for most of the end points, and identifies data gaps including the submission of original toxicity studies on POEA-t, as well as clarification of certain other issues.
    2. Industry has not been requested, yet, to provide the available studies and information.
    3. There are tox studies on tallowamine available that have not been requested by authorities. EFSA was unable to conclude on a risk assessment without these. http://www.efsa.europa.eu/en/efsajournal/pub/4303.
    4. EFSA did not conduct a comprehensive review of the safety of tallow amines (and a full assessment was not submitted) because this was beyond the scope of the Annex 1 renewal process for glyphosate.
    5. It would therefore appear inappropriate for ANSES to justify its intention to withdraw on imminent health risks, as the assessment would have been conducted based on very limited information and therefore is incomplete.
    6. If ANSES conclusions are indeed based on the data available to EFSA or the conclusions of the EFSA evaluation, then it would seem more accurate to position any intention to ban as a precautionary approach.
- The consequences of the positioning of the withdrawal need to be considered carefully because of other approved uses in other fields, including personal care and hygiene consumer products. Logically, if the ban is due to an immediate risk to health and safety issue, these other uses should be banned at the same time.
    - Singling out POEA-t in glyphosate containing products seems inappropriate, as many more surfactants are registered and used in PPP and other fields. To our knowledge, the relative toxicity of different surfactants has not been performed by ANSES.
    - The consequences of this ban if referring to human health risks have the potential to go beyond France and would potentially have global and trade impact. It is therefore of essence that any intention to ban does not refer to imminent human health risk.

Support materials:

Opinion from EFSA on tallowamine (Nov 2015):

EFSA Statement: http://www.efsa.europa.eu/en/efsajournal/pub/4303

The genotoxicity, long-term toxicity and carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential of POE-tallowamine should be further clarified. There is no information regarding the residues in plants and livestock. Therefore, the available data are insufficient to perform a risk assessment in the area of human and animal health for the co-formulant POE-tallowamine.

Full assessment here:

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4303.pdf

EFSAs one-pager on the assessment of glyphosate (Nov 2015):
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf
EFSA acknowledges the use of tallowamine as a surfactant.

From: AGUSTIN, MELISSA [AG/1000]
Sent: Tuesday, March 29, 2016 11:11 PM
To: BICKEL, ANNA M [AG/1000] <[redacted] MURPHY, STEPHANIE L [AG/1920] [redacted] RAMSAY, JONATHAN [AG/5040[redacted] CARPINTERO, DAVID [AG/5040] [redacted] HEERING, DAVID C [AG/1000] [redacted]
Cc: JACKSON - GHEISSARI, AMELIA ELIZABETH [AG/1920] [redacted]>; REYNOLDS, TRACEY L [AG/1000] [redacted]
Subject: RE: French Embassy visit

Thanks, Anna.
Christophe is a significant player in the French government. Part of that shows up in the bio but we should highlight for Pierre. And, given this, I'd also suggest that add some of our policy interests, outside of the biological space, to the objective for the visit. Jonathan and Stephanie should be able to help us here.
Melissa

From: BICKEL, ANNA M [AG/1000]
Sent: Tuesday, March 29, 2016 3:52 PM
To: MURPHY, STEPHANIE L [AG/1920]; RAMSAY, JONATHAN [AG/5040]; CARPINTERO, DAVID [AG/5040]; HEERING, DAVID C [AG/1000]
Cc: AGUSTIN, MELISSA [AG/1000]; JACKSON - GHEISSARI, AMELIA ELIZABETH [AG/1920]; REYNOLDS, TRACEY L [AG/1000]
Subject: RE: French Embassy visit

Dear All,
I have attached the Briefing Document for the French Embassy visit on April 8, 2016. I have also included the itinerary in case that is of interest.

Please let me know if you would like any additions made to the Briefing document by the end of this week.

I would like to send the final version to all of the Monsanto participants this Friday.

Thank you,
Anna

Anna Bickel
Regulatory Policy and Scientific Affairs
Science Communications Manager
[redacted]

From: AGUSTIN, MELISSA [AG/1000]
Sent: Tuesday, March 29, 2016 1:49 PM
To: JACKSON - GHEISSARI, AMELIA ELIZABETH [AG/1920]; REYNOLDS, TRACEY L [AG/1000]; BICKEL, ANNA M [AG/1000]
Cc: MURPHY, STEPHANIE L [AG/1920]; RAMSAY, JONATHAN [AG/5040]; CARPINTERO, DAVID [AG/5040]; HEERING, DAVID C [AG/1000]
Subject: French Embassy visit

Tracey, Amelia and Anna,

Could you forward the latest briefing paper for the French Embassy visit to our colleagues in the CC: line for additional inputs? In speaking with Jonathan this morning, he had some ideas on how we may want to position some proactive messaging on policy issues outside of the focus of the visit. Given the profile of this visitor, we want to make sure we are thinking about leveraging this beyond their originally expressed interest.

Melissa