Message

From: Monika Szablicka [monika.szablicka@envigo.com]
Sent: 6/22/2017 2:31:26 PM
To: Odusote, Gloria [odusote.gloria@epa.gov]
CC: Melissa Elliott [melissa.elliott@envigo.com]; David Howes [david.howes@envigo.com]
Subject: RE: Concerning Your Case
Attachments: 20170620 Additional Information and Exposure revised Nomoto-Okata.docx

Dear Gloria,

Our client has sent us some update. They confirm that **all industrial process occur in a closed-system and residual monomer in waste water is treated by the activated sludge method and discharged**.
Please can you refer to the revised document attached?

Please can you let me know if this update is sufficient for you to proceed?

Thank you.

Kind regards
Monika

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: 22 June 2017 15:10
To: David Howes; Monika Szablicka
Cc: Melissa Elliott
Subject: RE: Concerning Your Case

Hi Monika and David,

Do you have any update about your case? I need an update or a request for suspension by today as I am out of the office tomorrow and the Day 90 is on Sunday.

Best,
Gloria

From: David Howes [mailto:david.howes@envigo.com]
Sent: Tuesday, June 13, 2017 11:12 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>; Monika Szablicka <monika.szablicka@envigo.com>
Cc: Melissa Elliott <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria

I have no specific concerns and I am available to call whenever is most convenient to you.

Please let me know when I should call.

Best regards
David

David Howes
Expert Consultant

Regulatory Consulting
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F +44 (0) 1480 892 362
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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: 13 June 2017 13:40
To: Monika Szablicka; David Howes
Cc: Melissa Elliott
Subject: RE: Concerning Your Case

Hi Monica and David,
I cannot make calls outside the U.S but you are free to call me at 202-564-1845. David, do you have specific questions you would like me to answer? I want to make sure that before we talk, I have the answers you need and if I do not, I can get one of the scientists in the phone call as well.

Best,
Gloria

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Tuesday, June 13, 2017 5:32 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>; David Howes <david.howes@envigo.com>
Cc: Melissa Elliott <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Melissa informed me that she agreed to the extension, I think we do not have any other option. I am not in the office today but I have asked my colleague who is our Expert Consultant to discuss with you EPA further concerns regarding the PMN substance exposure. His name is David Howes and he is also included in this correspondence. Please will you be able to contact him at the following number:
+44(0)1480892269. David will be in the office until 5pm UK time.

Thank you.
Kind regards
Monika

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: 12 June 2017 14:05
To: Monika Szablicka
Subject: RE: Concerning Your Case

Also, your day 90 is here. Would you like to request a suspension? Also, I was wondering if we could talk about the report you sent.

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Monday, June 12, 2017 1:47 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you for your reply and I am sorry I could not call on Friday as I left my office before I received your message. I am checking with the technical contact who told us about the new person, assigned to our polymer case,at EPA.

Kindest regards
Monika

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: 09 June 2017 18:15
To: Monika Szablicka
Subject: RE: Concerning Your Case

Hi Monika,

I don't see any reassignments for that case. If you are free, can you please call?

Best,
Gloria

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Friday, June 9, 2017 12:55 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Melissa Elliott <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Following on from my email please can I ask you to provide me with contact details for the Program Manager for our polymer case. I have found out from our technical contact that the person has changed again and it is now Gloria Duclate. I would like to send her some information regarding our case.

I thank you in advance for your help.

Kindest regards
Monika

Monika Szablicka
Regulatory Specialist
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ENVIGO

From: Monika Szablicka
Sent: Friday, June 09, 2017 4:27 PM
To: 'Odusote, Gloria'
Subject: RE: Concerning Your Case

Dear Gloria,

We have obtained the information as per attached. The client confirmed that it does not contain CBI.

Please can you let me know if it is sufficient for the EPA final assessment?

Thank you.

Kindest regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Thursday, June 08, 2017 10:14 PM
To: Monika Szablicka
Subject: RE: Concerning Your Case

Hi Monika,
Sure you can but if it's about exposure, I may not have much to tell you.

Best,
Gloria

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Thursday, June 8, 2017 11:22 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

I have some information from our client. Do you think I could send it to you for your review before I submit this via CDX?

Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Wednesday, June 07, 2017 4:10 PM

To: Monika Szablicka
Subject: RE: Concerning Your Case

Hi Monika,
Sorry for the delay in response. I have been out of the office for some time.
That is the only number I have for him. Have you still not heard from him?

Also do you have any updates about your case with me? The Day 90 is this week.

Best,
Gloria

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Thursday, May 25, 2017 8:44 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Melissa Elliott <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

I am contacting you again for the P-16-0509 case. Unfortunately I can not get hold of the Program Manager Jeff Bauer via phone. Please can you provide me with his phone number?

Thank you.

Best regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, May 16, 2017 6:55 PM
To: Monika Szablicka
Subject: RE: Concerning Your Case

Hi Monika,
Jeff Bauer is the Program Manager for your case. I'm not sure when the consent order will be developed especially with the current backlog. His phone number is 202-564-9042.

Best regards,
Gloria

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Tuesday, May 16, 2017 9:30 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Melissa Elliott <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Would it be possible please for you to contact the Program Manager at EPA Rose Allison, for our other PMN which is related to this submission. It is P-16-0509. We have submitted response to the action letter and we understand that the consent order will be issued by June 5th. We have however not heard anything from EPA. Please can you confirm this as I am unable to contact our technical contact at the moment.

I would really appreciate your help regarding this.

Thank you.

Kind regards
Monika

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ENVIGO

From: Monika Szablicka
Sent: Tuesday, May 16, 2017 2:22 PM
To: 'Odusote, Gloria'
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you very much.

Kindest regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, May 16, 2017 1:53 PM
To: Monika Szablicka
Subject: RE: Concerning Your Case

Hi Monika,
Sure, let me know if there is any way I can help.

Best,
Gloria

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Tuesday, May 16, 2017 8:39 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Our client has requested today a suspension of 15 days. Please can you let me know if this is acceptable?

Thank you.

Kind regards
Monika

Monika Szablicka
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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Friday, May 12, 2017 6:58 PM
To: Monika Szablicka
Subject: RE: Concerning Your Case

Hi Monika,
Please let me know if I misunderstood you but I took your previous message as you asking for a 7 day suspension. Please let me know if that is not the client's request and I can rescind the suspension.

Best regards,
Gloria

From: Monika Szablicka [mailto:monika.szablicka@envigo.com]
Sent: Friday, May 12, 2017 12:39 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Melissa Elliott <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you very much for your confirmation. I have asked if this data is available. I will keep you updated.

With very best regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Thursday, May 11, 2017 6:58 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monika,
A week should be fine, if they think they have monitoring data or equipment information detailing the exposures. I can let you know if you'll need to request another suspension.

Best,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Thursday, May 11, 2017 10:27 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you for contacting me. I am sorry I am not in the office today.
Today our client informed me that they will be preparing the additional information regarding no inhalation and environmental exposure. They will however need about a week for this. Will this be acceptable to EPA please?

Thank you.
Kind regards
Monika

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: 11 May 2017 15:06
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monika,
Do you want to call? I am not sure what kind of information the company might want to resubmit and I might be able to give better advice if we deal with the specifics.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Wednesday, May 10, 2017 11:56 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Our client is preparing the final response however they asked me to confirm with you the following:
If they decide to select Option 3 from the action letter and withdraw the PMN how soon they can re-submit? They are considering changing some information provided in the original PMN. This is very hard decision for them.

Please can you advise?

Thank you.

Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, May 08, 2017 7:35 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monika,
If you provide information that there is no inhalation and environmental exposures, the testing would no longer be upfront.
You would still need to respond to the action letter, checking the option that you are providing more information and giving us the time to review the information and write the consent order.

Best,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Monday, May 8, 2017 10:14 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you very much for your time earlier on. There was one question which I would appreciate you clarification on. If we provide an information that there is no inhalation possibility - would we still need to conduct the studies (OECD 422 and OECD 486)? Would we still have to respond to the action letter?

Thank you
Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, May 08, 2017 1:31 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monika,
I'm free today. Feel free to call anytime.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Monday, May 8, 2017 8:23 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Elliott, Melissa <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Please can you let me know if you are available for the call today?

Thank you.
Kind regards
Monika

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ENVIGO

From: Szablicka, Monika
Sent: Friday, May 05, 2017 9:49 AM
To: 'Odusote, Gloria'
Cc: Elliott, Melissa
Subject: RE: Concerning Your Case

Dear Gloria,

Please can you let me know when it will be convenient for you so I can call you?

I will be in a meeting until 11am UK time and then between 12.30-14.00pm UK time.

Thank you.
Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Thursday, May 04, 2017 7:29 PM
To: Szablicka, Monika
Cc: Elliott, Melissa
Subject: RE: Concerning Your Case

Hi Monica,
In answering this, I would have to explain the test. Since that is CBI, it would probably be best to explain this over the phone.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Thursday, May 4, 2017 11:43 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Elliott, Melissa <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you for your kind assistance. Our client is considering the regulatory options and they have some queries. Please can you help us understanding the engineering report, i.e. is there a specific part which we should pay attention to?

In the EPA action letter it is stated that there is a concern for acute toxicity however we have submitted the test report on acute toxicity (please refer to Attachment no. 12 in the original PMN). Additionally, and also as stated in the engineering report the compound does not raise concerns regarding mutagenicity or genetic toxicity in vivo and is unlikely to be carcinogenic. We would really appreciate if you could give us more details as to why the OEDC 422 and OECD 486 are required?

Our client is also considering an analog substance which could possess any data on the health effects information but it is difficult to identify the appropriate analog.

Another question which our client has is whether we can change the application without selecting these 3 options?

Please can you give us your comments regarding the above?

Thank you.

Kind regards
Monika

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: 27 April 2017 18:09
To: Szablicka, Monika
Cc: Elliott, Melissa
Subject: RE: Concerning Your Case

Hi Monika and Melissa,
Yes, you still have the current suspension and since we have been talking, the suspension applies to the action letter as well. Please let me know if there is any way that I can help speed up the process. With the current changes in the EPA, wrapping up the review time for these chemicals has become a priority.

Best regards,
Gloria Odusote

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Wednesday, April 26, 2017 7:33 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>; Elliott, Melissa <melissa.elliott@envigo.com>
Subject: RE: Concerning Your Case
Importance: High

Dear Gloria,

I am aware about the two separate 15 day suspensions to allow us for any review and actions from the engineering report. However I think the 30 days response to the EPA action letter (dated Mar27, 2017) ends today please can you therefore confirm that the extension also applies to this? Unfortunately our client is still considering their final decision.

I appreciate your response at your earliest convenience.
Thank you.

Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Wednesday, April 12, 2017 1:56 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
Do you have the fax number yet? Also your day 90 is coming up. Would you like to request a suspension while you read through the report ad come up with the new information?

Bets regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Wednesday, April 5, 2017 10:15 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

I am sorry for this. I am checking with the technical contact if the fax number is available at her side.

Thank you.

Kind regards
Monika

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envigo.com

ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, April 04, 2017 9:14 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
I hope this email finds you well. I have the engineering report for your case. Do you have a domestic fax number?

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Tuesday, March 28, 2017 10:46 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you very much for contacting me with respect to our submission.

I will summarize your concerns with regards to the substance and will inform our client respectively while waiting for the official EPA letter.

If I understood correctly, may I request the engineering controls report to be sent to us via fax?
The number for the fax is: (0044)01480 892362.

Thank you.
Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, March 28, 2017 2:09 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
Can you please call me again. Another submitter called me right before you called.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Tuesday, March 28, 2017 4:50 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Gloria,

Thank you for your reply. Yes I will call you at 9am EST (2pm UK time).

Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, March 27, 2017 9:01 PM
To: Szablicka, Monika
Subject: RE: Concerning Your Case

Hi Monica,
I know it is very late your time. Would you be free to talk tomorrow at 9am EST to talk about your case. Unfortunately, I can't list the PMN number in an email to you as that is CBI.

Best regards,
Gloria

From: Szablicka, Monika [mailto:monika.szablicka@envigo.com]
Sent: Monday, March 27, 2017 11:58 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Concerning Your Case

Dear Ms Odusote,

Thank you for contacting me. I have tried to calling you just now but I understand that you were not available. Please can you let me know which case number you were referring to in your email?

Thank you
Kind regards
Monika

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ENVIGO

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, March 27, 2017 3:31 PM
To: Szablicka, Monika
Subject: EPA: Concerning Your Case

Hi Ms. Szablicka,
My name is Gloria Odusote and I am the Program Manager for your case. I would like to give you an update on your case.

Please call me at the number below at your earliest convenience.

Best regards,
Gloria Odusote

Gloria Odusote
Chemical Control Division
EPA East
1200 Pennsylvania Ave. NW
Room 4133G, Mail Code 7405M
Washington, DC 20460
202 564-1845
Fax 202 564 9490

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