

**RFI7098**

**All communications and meetings between Defra and Oxitec Ltd. since 1st January 2013.**

EMAIL FROM OXITEC TO DEFRA 3/10/14

-----,

I am sending you a presentation that was done recently in Brazil by the Panamanian Biosafety Commission representative Judith Vargas, regarding the procedure used for the Oxitec mosquito in Panama.

I'd like to follow this up with a call next week – is there any time that would be best for you ?

Thanks

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ANNEX 1 ATTACHED – PANAMA RELEASE PRESENTATION

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EMAIL FROM OXITEC TO DEFRA 16/9/14

Dear -----

Genetically engineered diamondback moth shipments that have been made to date from Oxitec Ltd, UK to Cornell University, USA have been for laboratory evaluation and are therefore outside the scope of the transboundary movements legislation.

With best regards

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EMAIL FROM DEFRA TO OXITEC 15/9/14

Subject: DIAMONDBACK MOTHS EXPORT TO THE US

Dear -----

We have received the following query from the Commission:

“Please see the following regarding a forthcoming field trial in the US  
[http://www.aphis.usda.gov/brs/fedregister/BRS\\_20140828b.pdf](http://www.aphis.usda.gov/brs/fedregister/BRS_20140828b.pdf). Please can you clarify if the initial shipment of the GM diamond black moths from the UK was for the purposes of contained use.”

We’d be grateful if you could clarify the status of any moth shipments made and whether there they fall within the scope of the transboundary movements legislation.

Best wishes

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EMAIL FROM OXITEC TO DEFRA 12/5/14

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I have made one comment and one amendment in the attached.

I think it is important to indicate that an import permit was also issued by the Panamanian authorities, as all insects are shipped to the rearing facility first, for rearing, prior to going into the field.

Although I am out of the office for the rest of the week, I am available most of tomorrow on email.

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ANNEX 2 ATTACHED – DRAFT DEFRA REPLY TO LETTER ENQUIRING ABOUT OXITEC

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EMAIL FROM OXITEC TO DEFRA 1/4/14

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Please forgive the delay in response to your question

I enclose the risk assessment that was submitted to the Panamanian authorities by the Gorgas Institute, based on information supplied by Oxitec to the Gorgas Institute. I have not been able to obtain a risk assessment report directly from the Panamanian competent authority.

I also enclose the import permit received from the Panamanian competent authority for the import of Oxitec materials

As usual I ask that individual names/addresses and telephone numbers are redacted.

With best regards

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ANNEX 3, 4 & 5 ATTACHED – PANAMA NOTIFICATION DOCUMENTS

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DEFRA TO OXITEC 10/3/14

Subject: FW: FW: GMO transboundary notification: information request - Panama. ref. RFI4379

Dear -----

To see the latest email from ----- on the Panama export. She has stated that Oxitec has to supply the risk assessment and that if a breach of the regulations has taken place Defra should conduct a full investigation. We don't intend to proceed with an investigation but is there any chance of you now getting hold of the risk assessment prepared by the Panama authorities, or can you let us have a reason why they won't release it? Do we know for sure that they have actually done one?

Best wishes.

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CORRESPONDENCE ATTACHED TO THIS EMAIL:

From: -----

Sent: 07 March 2014 12:49

To: -----

Subject: Re: FW: GMO transboundary notification: information request - Panama. ref. RFI4379

Dear -----,

REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 July 2003 on transboundary movements of genetically modified organisms states:

## Article 4

### Notification to Parties and non-Parties of import

The exporter shall ensure notification, in writing, to the competent authority of the Party or non-Party of import prior to the first intentional transboundary movement of a GMO intended for deliberate release into the environment and destined for the use specified in accordance with Annex I, point (i). The notification shall contain, as a minimum, the information specified in Annex I. The exporter shall ensure the accuracy of the information contained in the notification.

## Article 5

### Cases of non-decision

1. A failure by the Party of import to acknowledge receipt of a notification or to communicate its decision shall not imply its consent to an intentional transboundary movement. No first intentional transboundary movement may be made without prior written express consent of the Party or, where appropriate, non-Party of import.

## ANNEX I

### INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLE 4

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the GMO, as well as the domestic classification, if any, of the biosafety level of the GMO in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or

parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms

and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or

organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics

of the GMO.

(i) Intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing

detectable novel combinations of replicable genetic material obtained through techniques listed in Annex I A, Part 1

of Directive 2001/18/EC.

(j) Quantity or volume of the GMO to be transferred.

(k) A previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation,

disposal and contingency procedures, where appropriate.

(m) Regulatory status of the GMO within the State of export (for example, whether it is prohibited in the State of

export, whether there are other restrictions, or whether it has been approved for general release) and, if the GMO is

banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.

The exporter is therefore required to provide an ERA consistent with 2001/18/EC(Article 5 and Annex I(k)) before the importer makes a decision and gives its prior written consent to the import (Article 5).

Although Panama has approved open release experiments, this does not mean it has approved the import as required by Article 5, nor does this substitute for the exporter's responsibility to provide an ERA consistent with 2001/18/EC. Thus the following documents are missing:

1. The ERA consistent with 2001/18/EC which is legally required to be provided by Oxitec as part of the notification process;
2. The prior written express consent of Panama to the import of GM mosquito eggs.

We would still like copies of these documents, which we are entitled to receive under Article 6 of Regulation (EC) No 1946/2003 and environmental information laws.

If these documents do not exist and the export has already taken place, the only possible conclusion is the Oxitec has breached the requirements of the regulations and we would expect Defra to be conducting a full investigation.

Regards,

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EMAIL FROM OXITEC TO DEFRA 25/2/14

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Thank you for the opportunity to comment. In the notification for transboundary movement I included a copy of the Panamanian permit for deliberate release in the environment, which addresses -----'s point 2 : A copy of the prior written express consent of the Party of import (i.e. Panama) as required under Article 5 of Regulation (EC) No 1946/2003. Did you already send that with the earlier answer ? If not I propose that could be included in your response to address the second point.

No shipments for intentional introduction into the environment have been made to Panama to date, despite press reporting.

Best regards

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EMAIL FROM DEFRA TO OXITEC 25/2/14

Subject: RE: GMO transboundary notification: information request - Panama. ref. RFI4379

Dear -----

----- has asked for more information on the Panama shipment. I attach a draft reply but please let me know if you wish to add anything to address her points more fully as she will probably be putting something on the ----- website.

"Dear -----

Thank you for your query. We have sent you everything we received from Oxitec on the Panama notification. We understand the Panamanian authorities carried out their own risk assessment based on the data submitted and this was not made available to Oxitec."

Best wishes

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CORRESPONDENCE ATTACHED TO THIS EMAIL:

From: -----

Sent: 25 February 2014 10:49

To: ----- (Defra)

Subject: Re: GMO transboundary notification: information request - Panama. ref. RFI4379

Dear -----,

I note that the previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC, required to be provided by the exporter under Regulation (EC) No 1946/2003 (Article 4 and Annex I(k)) is missing from the notification.

Under the Freedom of Information Act/EIRs, I am seeking:

1. A copy of the exporter's (i.e. Oxitec's) previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC; 2. A copy of the prior written express consent of the Party of import (i.e. Panama) as required under Article 5 of Regulation (EC) No 1946/2003.

I understand from the press in Panama that Oxitec was due to take the GMmosquito eggs for open release to Panama last week:

<http://www.elsiglo.com/mensual/2014/02/11/contenido/750929.asp>

Best regards,

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On 10/02/2014 09:46, ----- (Defra) wrote:

Dear -----

I attach the Panama notification document we received from Oxitec.

Best wishes

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From: -----

Sent: 07 February 2014 16:02

To: ----- (Defra)

Subject: Re: GMO transboundary notification: information request -

Panama. ref. RFI4379

Dear -----,

I am just checking whether my FoI still stands or whether I need to keep repeating it?



(If you have it) I would like a copy of the transboundary notification for Oxitec's exports to Panama, including all accompanying documents.

F.y.i. the open release has been delayed until at least March (maybe longer) due to emergency health measures for the dengue epidemic.

Best wishes,

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On 28/01/2014 09:22, ----- (Defra) wrote:

Dear -----

Nothing at the moment but Oxitec have said they will be sending us the Panama documents.

Best wishes

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From: -----

Sent: 27 January 2014 14:43

To: ----- (Defra)

Subject: Re: GMO transboundary notification: information request -

Panama. ref. RFI4379

Dear -----,

Could you please let me know if you have had any new transboundary notifications since my last request? And, if so, please supply me with copies of the documents.

The open release of Oxitec's GM mosquitoes in Panama is now scheduled for 15th February.

Thanks,

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On 14/01/2014 15:45, ----- (Defra) wrote:

Dear -----

We haven't received any new notifications. I have checked with Oxitec and they have told me all shipments to Panama to date have been for contained use so the transboundary regulations have not applied. Oxitec will submit a transboundary notification as soon as it is required.

Best wishes

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From: -----

Sent: 14 January 2014 14:05

To: ----- (Defra)

Subject: Re: GMO transboundary notification: information request -

Panama. ref. RFI4379

Dear -----,

Could you please let me know if you have had any new transboundary notifications since my last request? And, if so, please supply me with copies of the documents.

We are aware that new open release experiments using Oxitec's GM mosquitoes have been approved in Panama (which should require a transboundary notification):

<http://horacero.com.pa/nacionales/102215-minsa-aprueba-uso-de-mosquito-t>

[ransgenico-en-el-combate-contra-el-dengue.html](#)

Thanks,

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On 12/11/2013 11:06, ----- (Defra) wrote:

Dear -----

Nothing new to report

Best wishes

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From: -----

Sent: 12 November 2013 11:06

To: ----- (Defra)

Subject: Re: GMO transboundary notification: information request -

Panama. ref. RFI4379

Dear -----,

Could you please let me know if you have had any new transboundary notifications since my last request? And, if so, please supply me with copies of the documents.

Thanks,

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On 17/09/2013 10:45, ----- (Defra) wrote:

Dear -----

Nothing new to report

Best wishes

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EMAIL FROM OXITEC TO DEFRA 10/2/14

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Yes this is Ok with us.

Thanks

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EMAIL FROM DEFRA TO OXITEC 10/2/14

Subject: FOI REQUEST - PANAMA MOSQUITOES TRANSBOUNDARY NOTIFICATION

Dear -----

We have had as expected an FOI request from ----- for the documents associated with the Panama transboundary notification. Are you happy for us to send her what you gave us?

I am copying this to ----- in the Commission as on previous occasions ----- asked them for the same information.

ANNEX 6 ATTACHED – PANAMA NOTIFICATION

Best wishes

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E MAIL FROM OXITEC TO DEFRA 29/1/14

Subject: Oxitec Transboundary Movement Notification for Panama

Please find attached a transboundary movement notification under Regulation 1946/2003 for shipment of Aedes aegypti OX513A to Panama for intentional introduction into the environment.

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ANNEX 6 ATTACHED – PANAMA NOTIFICATION

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EMAIL FROM OXITEC TO DEFRA 2/10/13

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I am out of the office for most of this afternoon so will get back to you tomorrow Hope that is ok for you time wise ?

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EMAIL FROM DEFRA TO OXITEC 2/10/13

And the final tranche:

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EMAIL FROM DEFRA TO OXITEC 2/10/13

Subject: RE: Parliamentary Question about GM insect exports

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I've tried separately to send you what I think is all the documentation you submitted to us in February 2011 for the notifiable Brazilian export. However the email came back as 'undeliverable' because of a limit on what your system will receive (the attempted email was 9Mb). So if you'll bear with me I'll send the material in several tranches.

I'd like you to confirm that we're referring to all the relevant docs, and whether you think any other redactions are needed on grounds of commercial confidentiality, beyond those we made previously when releasing material in response to a formal information request.

The first tranche of documents is attached.

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EMAIL FROM OXITEC TO DEFRA 2/10/13

Subject: RE: Parliamentary Question about GM insect exports

Thanks -----,

I think this accurately reflects the situation.

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EMAIL FROM DEFRA TO OXITEC 2/10/13

Subject: RE: Parliamentary Question about GM insect exports

Thanks -----,

I've now reworked the answer to this:

The Government has not received any documents from Oxitec Limited in relation to exports of genetically modified (GM) insects to Spain, Italy, Morocco or Panama. Exports to other EU countries do not need to be notified to the Government, nor do exports to non-EU countries where the GM organisms are intended to be kept in contained-use facilities. We shall place in the Library a copy of the documents supplied by Oxitec for its export of GM mosquitoes to Brazil, some of which were made available previously in response to an earlier Parliamentary Question. As before, some material has been redacted for reasons of commercial confidentiality.

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EMAIL FROM OXITEC TO DEFRA 1/10/13

Subject: RE: Parliamentary Question about GM insect exports

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Many thanks, the situation is correctly described however I was wondering if we can deal with Italy under the intra-EU movements, rather than single it out for special comment. It appears rather a hostage to fortune as it is currently stated, and if it is not required under the TBM anyway that seem to be appropriate.

I am working from home tomorrow so if you need to reach me I can be contacted on my mobile (reception can be poor where I live, so I have provided an alternative number as well)

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EMAIL FROM DEFRA TO OXITEC 1/10/13

Subject: Parliamentary Question about GM insect exports

-----,

As discussed, here is the PQ we've received and my initial stab at a draft reply. We want to make sure that we provide Parliament with accurate information, and therefore I'd be grateful if you could confirm that I've correctly described the situation from your perspective. We'll check with you whether there is anything commercially sensitive in the documentation you provided for the Brazilian export, outwith the risk assessment paper.

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ATTACHED TO THIS EMAIL WERE THE FOLLOWING DOCUMENTS . AS WE NOW ONLY HAVE THIS EMAIL AS PART OF A LATER STRING WE NON LONGER HAVE THE ORIGINAL WITH THE ATTACHMENTS. THE 3 BRAZIL ATTACHMENTS WERE SENT TO YOU PREVIOUSLY IN AUGUST 2011 WITH OUR REPLY TO RFI3987.

> << File: Oxitec PQ Oct 2013.doc >>

> <RFI3987 Brazil - Redacted Aedes life cycle biology etc .pdf>

> <RFI3987 Brazil Appendix 4.pdf>

> <RFI3987 Brazil Appendix 4 too.pdf>

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EMAIL FROM OXITEC 11/2/13

Dear -----

There had not yet been a shipment to Panama from Oxitec and the permit received from Panama is only for contained use (attached). Consequently any shipment under this import permit is not notifiable under the Transboundary movement regulation 1946/2003

Best regards

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ANNEXES 4 & 5 ATTACHED – PANAMA NOTIFICATOIN

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EMAIL FROM DEFRA TO OXITEC 11/2/13

Subject: FW: Panama Oxitec transboundary notification request

Dear -----

We have received the attached request from ----- for the transboundary notification associated with the Oxitec mosquito egg shipment to Panama. Please could you send us the notification if this is caught by Regulation 1946/2003, or confirm that it does not need to be notified as was the case with some other shipments.

Best wishes

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Attached email:

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

From: -----

Sent: 08 February 2013 09:28

To: -----

Subject: FoI: Panama Oxitec transboundary notification request

Dear -----,

Panama reportedly approved the import of 500 GM mosquito eggs from the UK (Oxitec Ltd.) on 15th January 2013:

<http://www.prensa.com/impreso/panorama/zancudo-ingles-contra-el-dengue/155322>

Under the Environmental Information Regulations 2004 (EIRs), I am seeking a copy of the transboundary notification and accompanying documents, including the shipping invoice and risk assessment, as specified in Annex I of Regulation (EC) 1946/2003.

With thanks in advance for your assistance.

Best regards,

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